

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK**

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KYLE VILLARE, Individually and On Behalf of )  
All Others Similarly Situated, )  
  )  
  )  
Plaintiff, )  
  ) No. 1:19-cv-07319-ER  
v. )  
  )  
  )  
ABIOMED, INC., MICHAEL R. MINOGUE, )  
and TODD A. TRAPP, )  
  )  
Defendants. )  
  )

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**AMENDED CONSOLIDATED CLASS ACTION COMPLAINT FOR  
VIOLATION OF THE FEDERAL SECURITIES LAWS**

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**GLOSSARY OF TERMS AND ABBREVIATIONS  
USED IN AMENDED CONSOLIDATED CLASS ACTION COMPLAINT**

Term	Definition
CAM	Cardiology Account Manager, a Abiomed employee with medical device sales experience.
Cardiogenic shock	A condition in which a person's heart is unable to pump enough blood to meet the body's needs, and is most often caused by a severe heart attack.
Catheter	A flexible, hollow tube designed for insertion into passageways to drain fluids or distend body passages. In Impella devices, the catheter connects the blood inlet area to the blood outlet area, and allows for blood to flow between different areas of the heart.
Class III devices	Class III devices “are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which prevent a potential, unreasonable risk of illness or injury.”
Clinical Consultants	Nurses or care practitioners with experience in the cardiac space (but with little, or no, sales experience).
CMS	Centers for Medicare and Medicaid Services
DRG	Diagnosis Related Group
HDE	Humanitarian device exemption.
HUD	Humanitarian use device, which the FDA defines as “a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.”
IABP	Intra-Aortic Balloon Pump, a therapeutic device that helps the heart pump more blood. It consists of a long balloon attached to the end of a long, flexible tube called a catheter. The IABP is inserted percutaneously through the aorta, and is attached to a computer console that inflates and deflates the balloon as the heart beats. Similar to the pumps in the Impella Platform, the IABP provides temporary support to patients with heart trouble. Also similar to the pumps in the Impella Platform, the IABP has been approved by the FDA for use in PCI procedures, as well as for patients suffering from cardiogenic shock.

Impella Platform	The Impella portfolio that includes the Impella 2.5, Impella CP, Impella LD, Impella 5.0 (referred to together as the “Impella 5.0”), and Impella RP devices.
Infarct	An area of dead tissue that can occur in the heart as a result of inadequate blood flow.
Inotropes	Agents ( <i>i.e.</i> , drugs) that alter the force or energy of muscle contractions. Positive inotropes strengthen the force of the heartbeat, while negative inotropes weaken it. Positive inotropes can be used for patients suffering cardiogenic shock following cardiac surgery, and both types are sometimes used for patients who have suffered a heart attack.
LRP	The Company’s long range earnings plan.
LVAD	Left ventricular assist device.
PAS	Post-approval study.
PCI	Percutaneous Coronary Intervention. A PCI, formerly known as “angioplasty with stent,” is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis.
PMA	Premarket approval for sale to the public, based on a determination by the FDA that the device is safe and effective for its intended use.
Percutaneous	Refers to through the skin.
Protected PCI	A term coined by Abiomed to describe a PCI procedure performed with the assistance of an Impella pump.
RCM	Regional Clinical Manager, who was responsible for supervising the Clinical Consultants and lessening the CAM’s workload created by additional disconnect between Abiomed’s CAMs and Clinical Consultants.

Court-appointed Lead Plaintiff Local 705 International Brotherhood of Teamsters Pension Fund (“Local 705” or “Plaintiff”), individually and on behalf of all others similarly situated, by its undersigned counsel, hereby brings this Amended Consolidated Class Action Complaint (the “Complaint”) against Abiomed, Inc. (“Abiomed” or the “Company”), Michael R. Minogue (“Minogue”), and Todd A. Trapp (“Trapp”) (collectively, “Defendants”).<sup>1</sup> The allegations herein are based on Plaintiff’s personal knowledge as to its own acts and on information and belief as to all other matters, such information and belief having been informed by the investigation conducted by and under the supervision of Lead Counsel, which includes a review of: U.S. Securities and Exchange Commission (“SEC”) filings by Abiomed; securities analysts’ reports and advisories about the Company; press releases and other public statements issued by the Company; media reports about the Company; interviews of former employees of Abiomed with knowledge of the matters alleged herein; and consultation with an expert in the area of loss causation and damages.<sup>2</sup> Lead Counsel’s investigation into the matters alleged herein is ongoing and many relevant facts are known only to—or are exclusively within the custody or control of—the Defendants. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery. On behalf of itself and the class it seeks to represent, Plaintiff alleges as follows:

## **I. NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of all persons and entities who purchased or otherwise acquired the publicly traded securities of Abiomed during the period from May 3, 2018 to July 31, 2019, inclusive (the “Class Period”), and were damaged thereby.

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<sup>1</sup> Minogue and Trapp are collectively referred to as the “Individual Defendants.”

<sup>2</sup> Confidential witnesses (“CWs”) will be identified herein by number (CW-1, CW-2, etc.). All CWs will be described in the masculine to protect their identities.

The action is brought against Abiomed and certain of its officers for violations of the Securities Exchange Act of 1934 (the “Exchange Act”) and SEC Rule 10b-5 promulgated thereunder.

2. Abiomed is a Delaware company headquartered in Danvers, Massachusetts.

Founded in 1981, the Company is a provider of temporary mechanical circulatory support devices for the heart, and offers a continuum of care to heart failure patients. Abiomed develops, manufactures, and markets proprietary products that are designed to enable the heart to rest, heal, and recover by improving blood flow to the coronary arteries and end-organs and/or temporarily assisting the pumping function of the heart. The Company sells its products through direct sales and clinical support personnel in the United States, Canada, Europe, and Asia.

3. The Company’s “strategic focus and the driver of [its] revenue growth” is its family of Impella heart pumps. The Impella portfolio includes the Impella 2.5, Impella CP, Impella LD, Impella 5.0, and Impella RP devices (the “Impella Platform”). According to the Company, effectively all of its product and service revenue comes from its Impella devices.<sup>3</sup>

4. The pumps in the Impella Platform are considered Class III devices by the FDA<sup>4</sup> are approved for, or “indicated” for: (1) patients undergoing percutaneous<sup>5</sup> coronary intervention (“PCI”) procedures<sup>6</sup>; and (2) patients experiencing cardiogenic shock.<sup>7</sup> The Impella 2.5, Impella

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<sup>3</sup> The Impella pumps traditionally compete with the intra-aortic balloon pump, or IABP, a mechanical device that increases myocardial oxygen flow and indirectly increases cardiac output. Treatment with the IABP is the most common form of mechanical support for a failing heart.

<sup>4</sup> Class III devices “are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which prevent a potential, unreasonable risk of illness or injury.” *Premarket Approval (PMA)*, FDA.GOV, <https://www.fda.gov/medical-devices/premarket-submissions/premarket-approval-pma>. Class III devices require premarket approval (“PMA”) for sale to the public. PMA is based on a determination by the FDA that the device is safe and effective for its intended use.

<sup>5</sup> “Percutaneous” refers to through the skin.

<sup>6</sup> A PCI, formerly known as “angioplasty with stent,” is a non-surgical procedure that uses a catheter (a thin flexible tube) to place a small structure called a stent to open up blood vessels in (continued . . . )

5.0, and Impella LD were each approved for use and sale prior to 2010, and the Impella CP has been on the market since 2012.

5. In August 2015, Abiomed laid out the Company's long range earnings plan ("LRP") which included specific figures for the Company's revenue and operating margin goals over the following five years. Defendant Minogue and other Abiomed executives informed investors that by August 2020, Abiomed was expecting annual Impella revenues between \$1.2 billion and \$1.8 billion, while also growing operating margin to more than 30%. The Company based these projections on: (1) assumptions about the size of the available market for the Impella Platform; (2) the average selling price of the pumps; and (3) "the financial impact of unlocking new patient opportunities."<sup>8</sup> During the August 2015 presentation, Defendant Minogue also assured investors that the Company was projecting a top range of up to ***40% market penetration for revenue from Impella sales of more than \$1.8 billion.*** Defendant Minogue also reiterated that Abiomed would grow its operating margin to more than 30% while maintaining a gross margin of approximately 80%.

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(... continued)

the heart that have been narrowed by plaque buildup, a condition known as atherosclerosis. "Protected PCI" is a term coined by Abiomed to describe a PCI procedure performed with the assistance of an Impella pump. *PCI vs. Protected PCI: What is the Difference and Which One is Right for Me?*, IMPELLA.COM, <https://www.impella.com/blog/pci-vs-protected-pci-what-is-the-difference-and-which-one-is-right-for-me/>.

<sup>7</sup> Cardiogenic shock is a condition in which a person's heart is unable to pump enough blood to meet the body's needs, and is most often caused by a severe heart attack. *Patient Care & Health Information, Diseases & Conditions, Cardiogenic Shock*, MAYOCLINIC.ORG, <https://www.mayoclinic.org/diseases-conditions/cardiovascular-diseases/symptoms-causes/syc-20366739>.

<sup>8</sup> *Abiomed Outlines Long-Term Growth Strategy and Unveils Future Products at Annual Investor Conference*, ABIOMED.COM (Aug. 11, 2015), <http://investors.abiomed.com/news-releases/news-release-details/abiomed-outlines-long-term-growth-strategy-and-unveils-future>.

6. Between August 2015 and January 2019, Abiomed posted year-on-year revenue growth of more than 25% for fifteen (15) consecutive quarters, or approximately 3.5 years, while expanding its quarterly operating margins from 20.0% to 29.2%.

7. By the start of the Class Period in May 2018, Abiomed's growth was starting to plateau as its market penetration crested. Notwithstanding, Defendants still repeatedly assured the market as to the sustainability (and consistency) of the Company's 25-30% growth and Abiomed's opportunities for expanded use of the entire Impella Platform.

8. But the Company was ultimately forced to disclose, at the end of the Class Period: (i) decelerating year-on-year growth of only 19% for 4Q19 ended March 31, 2019 (compared to Q4 2018 growth rate of 40%); and (ii) year-on-year growth of just 15% for Q1 2020 ended June 30, 2019 (compared to Q1 2019 revenue growth of 36%) – a staggering slowdown in just two quarters. Moreover, by the start of 2018, the Company had only achieved 9% penetration of a potential 231,000 patients, and only 11% by the start of 2019, approximately half of the bottom end of the projections from the LRP.

9. During the Class Period, Defendants repeatedly and falsely emphasized to investors that the Company was set to achieve a significant and sustainable growth rate for its Impella devices. For example:

- (a) Defendant Minogue boasted that, "*And we're also maintaining this best in growth rate at a higher base and we're doing it while improving operating margin.*" ¶126.
- (b) Defendant Trapp hyped that, "*The business continues to expand rapidly, and our growth rates are in line with our 5-year vision outlined back in 2015. We will continue with our patients-first sustainable growth model.*" ¶127.

(c) Defendant Trapp represented that, “*Our platform of Impella products gives us the ability to make efficient investments in technology, which will lay the groundwork for improving clinical outcomes and sustaining long-term growth.*” ¶140.

(d) Defendant Minogue noted that, “*Abiomed is positioned for sustainable growth and building the field of heart recovery with disciplined execution*” and “*we are executing our plan for sustainable growth.*” ¶146.

(e) Defendant Trapp represented: “*We are well positioned to deliver our plan for 2019 and beyond*” and, “*So again, we'll continue to grow at a pace that we think is sustainable, and our goal is to remain one of the fastest-growing, most profitable medtech companies in the market.*” ¶148.

(f) Defendant Trapp boasted that, “*Keep in mind that the 30% was our 5-year operating margin target that we communicated 3.5 years ago. So we're ahead of that projection, and we will continue to drive for best-in-class performance.*” ¶157.

10. Moreover, throughout the Class Period, analysts parroted the Company’s growth story, echoing that Abiomed was “the cleanest growth story in medtech” (*Jefferies* 5/3/18); the “cleanest growth story in our space with expansive markets” (*Jefferies* 7/26/18); and that “Abiomed has a faster growth rate, better margin profile, monopolistic market structure, and an underpenetrated end market. This adds durability to the growth runway.” (*Raymond James* 7/26/18). *SunTrust Robinson Humphrey* noted that, “Our investment hypothesis for ABMD is predicated by what we perceive to be a very long tailed opportunity.” (11/1/18). *Guggenheim Securities* stated: “Longer-term, we continue to believe that Abiomed has a long growth runway ahead of it as it penetrates existing market opportunities that we estimate at \$6-7B. (*Guggenheim Securities* 1/31/19).

11. While Defendants repeatedly touted Abiomed's continued growth story, Defendants concurrently failed to disclose material information that Defendants were aware of or were reckless in not knowing that rendered their Class Period statements false and misleading. Because Defendants chose to speak on the issues described herein, they had a duty not to mislead investors or withhold material information that would make those statements misleading. Instead, Defendants created an impression of a state of affairs at Abiomed that differed in a material way from the one that actually existed.

12. Throughout the Class Period, Defendants' statements were materially false and misleading when made in that Defendants failed to disclose that:

- (a) The Company's growth rate was stalling because Impella had reached market penetration – *i.e.*, most hospitals and facilities already stocked Impella products which were used infrequently and rarely required reorder;
- (b) The Company could not convince doctors to regularly use the Impella pumps over the IABP, or beyond its narrow indications; thus Abiomed could not achieve significantly greater market penetration or sustain the growth rates the market had become accustomed to from the Company;
- (c) Abiomed's revenue growth began to stall as early as May 2018, or Q1 2019, a trend which worsened during the Class Period;
- (d) The growth expectations that Abiomed communicated internally to its sales employees and to the market were unattainable, in part, because hospitals were reluctant to stock extra Impella devices in their inventory and doctors remained reluctant to use Impella;
- (e) The Company did not have a sufficient plan in place to stem its declining revenue growth; and

(f) Because the Company carefully tracked patient outcomes and sales (including sales results by territory and through Re-Order Reports) and the Individual Defendants participated in meetings and calls, and had access to such sales reports, they knew or recklessly disregarded the deceleration in revenue growth.

(g) Consequently, Defendants' statements during the Class Period regarding the sustainability of the Company's growth and expanded adoption and use of the Impella Platform were materially false and misleading at all relevant times.

13. That the Company's Impella growth rate was stalling throughout the Class Period was well known within Abiomed—despite Defendants' successful efforts to withhold these facts from investors. Former Abiomed employees with knowledge of the Company's business confirm that the market for Impella products was already saturated at the start of the Class Period and the only way to increase Impella sales at hospital and clinics was to convince doctors to: (1) use the pumps in the Impella Platform instead of the IABP; and (2) expand their use of the pumps in the Impella Platform beyond the specific indications from the FDA, and thus use the Impella pumps more frequently.

14. As detailed and corroborated by multiple former employees of Abiomed, Defendants knew or recklessly disregarded that:

(a) Year-on-year revenue growth of 30% was unsustainable, primarily because the Company had already saturated the market for Impella pumps, and reorder performance was weak.

(b) Abiomed's sales practices throughout the Class Period—which were particularly aggressive at the end of the quarter—could not support the growth the Company

promised the market, and Abiomed sales representatives risked damaging long-term relationships with hospitals.

(c) Abiomed management's laser focus on the Company's share price during the Class Period led to extremely aggressive sales goals and questionable sales tactics.

(d) Doctors were reluctant to use Impella pumps, questioned their effectiveness, had issues with implantation, even looking for excuses not to use Impella pumps in some instances, and were unwilling to use the pumps beyond their very specific FDA indications.

(e) Abiomed's revenue growth was hindered by a disconnect between the Company's two types of field representatives - its Clinical Consultants and its Cardiology Account Managers ("CAMs") - who had competing interests. Clinical Consultants were nurses or care practitioners with experience in the cardiac space (but with little, or no, sales experience), while CAMs were Abiomed employees with medical device sales experience.

(f) Broader access to the Company's Impella clinical data would lead to additional questions about the integrity of the Company's data, and

(g) Tracking data from Salesforce related to Impella sales, implantation, and surgical outcomes showed that Impella use and, thus, reorder performance during the Class Period was weak.

15. Defendants' failure to disclose this information concealed risks related to the sustainability of the Company's growth, and deprived investors from properly analyzing the Company's current state of affairs and prospects and rendered Defendants' Class Period statements false and misleading. It was foreseeable that the value of Abiomed's securities would be adversely affected when the concealed risks materialized.

16. On February 4, 2019, the FDA issued a letter warning health care providers that one of Impella's heart pumps, the Impella RP device, was only meeting its primary survival endpoint in approximately 17% of the PAS patients, as opposed to the 73% in the pre-market clinical trials. In the letter, the FDA further noted that only 70% of the patients enrolled in the PAS would have met the strict enrollment criteria in the Impella RP's pre-market clinical trials.

17. In April 2019, the FDA approved revised labeling for Abiomed's Impella RP to include more information about patient selection and which patients might benefit the most from treatment with the device. In addition, the agency required Abiomed to make changes to the design of the PAS to include subgroup analyses and to establish a minimum number of patients in each subgroup.

18. The previously undisclosed risks about Abiomed's stalling growth were revealed through two disclosures, with the first on May 2, 2019, before the market opened, when Abiomed announced its financial and operating results for the fourth quarter and full year 2019 (Q4 2019/FY 2019). **For Q4 2019, the Company reported revenues of only \$207 million, more than \$10 million short of analysts' expectations, and up only 19% as compared to Q3 2019 revenue, and less than half of Q4 2018 growth of 40%.** Impella-related revenues and U.S.-only Impella revenues both fell short of estimates as a result of slower growth in patient utilization. Defendant Minogue admitted that, "Q4 did not meet our expectations. I take full responsibility for our disappointing performance given a soft March." The Company falsely blamed "customer confusion" stemming from the FDA's February 4, 2019, letter to health care providers regarding the Impella RP, which Abiomed claimed was misinterpreted by some media outlets and health care providers, and which provided competitor companies some edge with Abiomed's customers. However, Defendant Minogue assured the market that Abiomed "*already*

*initiated a plan of action to correct the course*" and Defendant Minogue was "**confident in our innovation and business today as well as long-term outlook for Abiomed.**" On this news, the price of Abiomed stock fell \$12.30 per share, or approximately 5% from a closing price of \$277.07 on May 1, 2019 to a closing price of \$264.77 on May 2, 2019.

19. On May 21, 2019, the FDA issued an update to its February 4, 2019 letter. The update noted that now approximately 28% of the PAS studies were meeting the primary survival endpoint of 30 days. The FDA attributed these results to patient selection; specifically, that doctors were electing to utilize the Impella RP device in patients who would have not qualified for the pre-approval clinical trials based on certain risk factors or circumstances surrounding the patients. In its conclusion, the FDA stated that the benefits of the Impella RP device still outweighed the risks **when used for its currently approved indication**, yet urged doctors to follow the revised labelling for the Impella RP, which include a patient selection checklist.

20. The previously undisclosed risks about Abiomed's stalled growth were fully revealed on August 1, 2019, before the market opened, when Defendants issued a press release announcing Abiomed's financial and operating results for the first quarter of fiscal year 2020. Among other results, **the Company disclosed Abiomed's third consecutive quarter of slowing revenue growth, reporting "first quarter fiscal 2020 revenue of \$207.7 million," which showed a flagging growth rate of just 15.4% compared to quarterly revenue of \$180.0 million for the same period the prior year. This represented a significant decrease in revenue growth from 1Q 2019 when the Company reported a year-on-year growth rate of 36%.** Commenting on the Company's disappointing financial results, Defendant Minogue revealed that the Company's "new training programs, organizational changes in distribution, and [ ] external initiatives. . . will require time to drive more growth in the future."

21. The Company also slashed its previously issued full-year 2020 guidance from total revenues in the range of \$900-945 million to total revenues in the range of \$885-925 million, **which fell roughly \$22 million short of market expectations.** Abiomed informed investors that in an effort to right the ship and kick-start growth, the Company adjusted both its overall strategy in the United States, as well as the Company’s distribution model. The Company also conceded that training physicians on “Impella access, closure and ICU management” was Abiomed’s “biggest obstacle” among doctors not currently utilizing Impella pumps. On this news, Abiomed’s stock price fell \$73.69 per share, or 26.45%, to close at \$204.87 per share on August 1, 2019.

22. Following the Company’s disclosure of its 1Q 2020 financial performance and revised guidance, *Investor’s Business Daily* published an article raising concern with Defendant Minogue’s prior public statements, titled: “This Medtech’s CEO Promised To ‘Correct The Course’ – That Didn’t Happen.” That article noted that “Abiomed stock collapsed Thursday after the medical technology company lagged Wall Street’s full-year guidance expectations by more than \$22 million.” The article also described Abiomed as “stuck in a trend of deceleration.”

23. Similarly, *Bloomberg* published an article on August 1, 2019, detailing investor concerns about the slowdown in revenue titled: “Heart-Pump Stock Goes From First to Worst as Growth Cools.” *Bloomberg* described Abiomed as “the worst performer in both the sector and the broader benchmark this year.” Also on August 1, 2019, *Stephens* published an analyst report noting that on the 4Q 2019 earnings call Defendants had indicated that the market was expecting an increase, not a decrease, in guidance, titled: “First Look: Not As Scripted, ABMD Missed Fiscal 1Q & Lowers FY20 Guidance.”

24. And *Guggenheim Securities* published an analyst report on August 1, 2019, titled “ABMD – Disappointing F1Q as Expected Recovery Fails to Materialize,” which attributed the Company’s disappointing dip in the Company’s revenue to a drop in Impella sales in the U.S. On August 2, 2019, *Guggenheim Securities* published another analyst report titled “ABMD – Lack of Recovery Suggests Deeper Issues; Downgrading to NEUTRAL,” which noted that Abiomed was struggling with structural issues, as well as an inability to compete with the IABP.

25. Moreover, unbeknownst to investors, during the Class Period, Abiomed insiders, including Defendant Minogue, had been heavily selling Abiomed stock in unusual and suspicious amounts totaling more than \$100 million while in possession of material non-public information regarding, among other things Abiomed’s stalled growth for Impella pumps, its sole product line. *Through these insider selling transactions, Defendant Minogue disposed of approximately 24.5% of his total shares of Abiomed stock that were available for sale during the Class Period* as compared to his trading of only 8.6% of his total shares of Abiomed stock that were available for sale during an equal length period prior to the Class Period.

26. As a result of Defendants’ false and misleading statements and omissions during the Class Period, the precipitous decline in the price of the Company’s securities and Plaintiff’s and other Class members’ significant resulting losses were foreseeable to Defendants.

## II. JURISDICTION AND VENUE

27. The claims asserted herein arise under Sections 10(b) and 20(a) of the Exchange Act (15 U.S.C. §§ 78j(b) and 78t(a)) and Rule 10b-5 promulgated thereunder by the SEC, 17 C.F.R. § 240.10b-5.

28. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1337, and Section 27 of the Exchange Act, 15 U.S.C. § 78aa.

29. Venue is proper in this District pursuant to Section 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b). Substantial acts in furtherance of the alleged fraud or the effects of the fraud have occurred in this Judicial District. Abiomed securities trade on the NASDAQ Stock Market (“NASDAQ”) located within this Judicial District.

30. In connection with the acts alleged in this complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the national securities markets.

### **III. PARTIES**

31. Court-appointed Lead Plaintiff Local 705 provides retirement benefits to collectively bargained members of Teamsters Local Union 705. The Plan and its assets are managed by a joint Board of Trustees equally represented by labor and management. Local 705 is a sophisticated institutional investor that had approximately \$1.3 billion in total pension assets under management as of July 31, 2020. As set forth in the Certification submitted herewith, Lead Plaintiff purchased or otherwise acquired Abiomed’s securities at artificially inflated prices during the Class Period and suffered damages upon the materialization of the concealed risks.

32. Abiomed is a Delaware corporation with its principal executive offices located at 22 Cherry Hill Drive, Danvers, Massachusetts 01923. Abiomed securities trade in an efficient market on the NASDAQ under the ticker symbol “ABMD.”

33. Defendant Minogue has served as Abiomed’s Chairman, President and Chief Executive Officer at all relevant times. Defendant

34. Defendant Minogue signed Abiomed’s annual reports and certifications pursuant to the Sarbanes-Oxley Act of 2002 (“SOX”) stating that the financial information contained in the Company’s financial reports was accurate and disclosed any material changes to Abiomed’s

internal control over financial reporting. Defendant Minogue also participated in each of the Company's quarterly earnings conference calls described herein. Defendant Minogue was a direct and substantial participant in the fraud.

35. Defendant Todd A. Trapp ("Trapp") has served as Abiomed's Vice President and Chief Financial Officer at all relevant times. Defendant Trapp signed Abiomed's annual reports and certifications pursuant to the SOX stating that the financial information contained in the Company's financial reports was accurate and disclosed any material changes to Abiomed's internal control over financial reporting. Defendant Trapp also participated in each of the Company's quarterly earnings conference calls described herein. Defendant Trapp was a direct and substantial participant in the fraud.

36. The Individual Defendants possessed the power and authority to control the contents of Abiomed's SEC filings, press releases, and other market communications. The Individual Defendants were provided with copies of Abiomed's SEC filings and press releases alleged herein to be misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or to cause them to be corrected. Because of their positions with Abiomed, and their access to material information available to them but not to the public, the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations being made were then materially false and misleading. The Individual Defendants are liable for the false statements and omissions pleaded herein.

## IV. SUBSTANTIVE ALLEGATIONS

### A. Background

37. Abiomed was founded in 1981 and is headquartered in Danvers, Massachusetts. Abiomed is a provider of temporary mechanical circulatory support devices for the heart. The Company develops, manufactures and markets proprietary products that are designed to improve blood flow to the coronary arteries and end-organs and/or temporarily assist the pumping function of the heart. Abiomed's products are used in the cardiac catheterization lab, or cath lab, by interventional cardiologists, the electrophysiology lab, the hybrid lab, and in the heart surgery suite by cardiac surgeons.

38. The Company's "strategic focus and the driver of [its] revenue growth" is the market penetration of its family of the Impella Platform.<sup>9</sup> All of the Company's product and service revenue comes from its Impella devices, which it sells through direct sales and clinical support personnel in the United States, Canada, Europe, and Asia. In both Fiscal Year 2019 ("FY2019"), ending March 31, 2018, and Fiscal Year 2020 ("FY2020"), ending March 31, 2019, Impella product sales accounted for 96% of Abiomed's total revenue. The indications for the pumps in the Impella Platform can generally be broken into two main categories: (1) patients undergoing PCI procedures; and (2) patients experiencing cardiogenic shock.

39. The Impella 2.5, Impella 5.0, and Impella LD were each approved for use and sale prior to 2010, and the Impella CP has been on the market since 2012. However, Abiomed really began to show substantial year-on-year revenue growth after the Impella RP was granted a

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<sup>9</sup> Abiomed received post market approval from the FDA for the next generation Impella pump, the Impella 5.5, after the Class Period, in September 2019. References to the "Impella Platform" or "Impella devices" herein do not include the Impella 5.5.

humanitarian device exemption (“HDE”)<sup>10</sup> from the FDA in the third quarter of Fiscal Year 2015 (“3Q 2015”). While devices under an HDE are subject to certain use and profit restrictions, Abiomed repeatedly touted the Impella RP, along with the rest of the Impella Platform, as a key growth driver for the Company.

40. Notably, Abiomed reported year-on-year revenue growth of 34% for 3Q 2015, and would report year-on-year revenue growth of more than 25% for the next fifteen quarters. Throughout that time, Abiomed repeatedly touted the effectiveness of the Impella pumps, especially relative to the use of an IABP, and the efforts the Company was making to expand the use of the Impella Platform to the hospitals that purchased the pumps, and the surgeons targeted to use them. But numerous observational studies comparing Impella pumps to an IABP showed higher incidences of death and bleeding in patients receiving Impella pumps, at higher costs.

### **1. The Impella Platform**

41. The pumps in the Impella Platform are considered Class III devices by the FDA. Class III devices require PMA for sale to the public. PMA is the FDA process of regulatory review to evaluate the safety and effectiveness of Class III devices. PMA is based on a determination by the FDA that the device is safe and effective for its intended use.

42. The Impella 2.5 is a percutaneous micro heart pump with an integrated motor and sensors. The primary purpose of the Impella 2.5 is for use by interventional cardiologists to

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<sup>10</sup> The FDA initially classified the Impella RP as a humanitarian use device (“HUD”), which the FDA defines as “a medical device intended to benefit patients in the treatment or diagnosis of a disease or condition that affects or is manifested in not more than 8,000 individuals in the United States per year.” *Humanitarian Use Devices and Humanitarian Device Exemption*, FDA.GOV, <https://www.fda.gov/science-research/pediatrics/humanitarian-use-devices-and-humanitarian-device-exemption>. When an HUD has been granted, an HDE “is exempt from the effectiveness requirements” imposed by the FDA, but is subject to certain profit and use restrictions.

maintain circulation by inserting the pump into the left ventricle of the heart through the left femoral artery. The Impella 2.5 can pump up to 2.5 liters of blood per minute. In March 2015, the Impella 2.5 received a PMA for use during both elective and high-risk PCI procedures, and in February 2018 received an expanded PMA for use in high-risk PCI.<sup>11</sup> In April 2016, the Impella 2.5 received a PMA for the treatment of patients suffering from cardiogenic shock following acute myocardial infarction, *i.e.*, a heart attack, or cardiac surgery, and in February 2018 received an expanded PMA for cardiogenic shock associated with cardiomyopathy.<sup>12</sup> The Impella 2.5 is also approved for use in Japan, the European Union (“EU”), and Canada.

43. The Impella CP is similar to the Impella 2.5, but is able to pump 3.5 liters of blood per minute, and is used by both interventional cardiologists in the cath lab, and by cardiac surgeons. In April 2016, the Impella CP’s PMA was supplemented to provide for treatment of patients undergoing cardiogenic shock, and covers indications for the Impella CP related to patients suffering cardiogenic shock following a severe heart attack or cardiac surgery, and similar to the Impella 2.5 also received an expanded PMA in February 2018 to cover patients suffering from cardiogenic shock associated with cardiomyopathy. In December 2016, the Impella CP received an expanded PMA to allow for use in both elective and high-risk PCI procedures. The Impella CP has been approved for sale in Japan and the EU. The Impella CP is

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<sup>11</sup> The definition of what qualifies as a “high-risk” PCI procedure is somewhat fluid, but high-risk PCI procedures generally involve patients “with a confluence of characteristics, including complex coronary artery disease . . . , hemodynamic compromise . . . , and clinical comorbidities.” Theodore A. Bass, MD, “High-Risk Percutaneous Coronary Interventions in Modern Day Clinical Practice” CIRCULATION: CARDIOVASCULAR INTERVENTIONS (Dec. 2015).

<sup>12</sup> Cardiomyopathy is a disease that makes it more difficult for the heart to pump blood to the rest of the body. *Patient Care & Health Information, Diseases & Conditions, Cardiomyopathy*, MAYOCLINIC.ORG, [https://www.mayoclinic.org/diseases-conditions/cardiomypathy/symptoms-causes/syc-20370709#:~:text=Cardiomyopathy%20\(kahr%2Ddee%2Do,dilated%2C%20hypertrophic%20and%20restrictive%20cardiomyopathy](https://www.mayoclinic.org/diseases-conditions/cardiomypathy/symptoms-causes/syc-20370709#:~:text=Cardiomyopathy%20(kahr%2Ddee%2Do,dilated%2C%20hypertrophic%20and%20restrictive%20cardiomyopathy).

also being studied for use before certain PCI procedures for its potential to reduce the infarct size resulting from those procedures.<sup>13</sup>

44. The Impella 5.0 and Impella LD are percutaneous micro heart pumps with integrated motors and sensors primarily for use during heart surgery. As noted above, these pumps are referred to collectively because they perform similar functions, really differing only in the way they are implanted, and are used in patients who require higher levels of circulatory support than an Impella CP can provide. The Impella 5.0 and Impella LD can pump up to 5 liters of blood per minute, which is potentially enough for full circulatory support. In April 2016, the FDA approved a PMA supplement that covered the use of the Impella 5.0 and Impella LD for patients undergoing cardiogenic shock following a severe heart attack or cardiac surgery. In February 2018, the Impella 5.0 and Impella LD received an expanded PMA that covered treatment for patients suffering heart failure associated with cardiomyopathy that leads to cardiogenic shock. The Impella 5.0 and Impella LD are also approved for sale in Japan and the EU.

45. The Impella RP is a percutaneous catheter-based axial flow pump that is designed to allow for more than four liters of blood per minute to flow through. The Impella RP, unlike the other pumps in the Impella portfolio, is designed to compensate for right heart failure. Abiomed touted the Impella RP as the “first percutaneous single access heart pump designed for right heart support to receive FDA approval.” The Impella RP was initially granted an HDE in January 2015, and received a PMA from the FDA in September 2017 with a very specific indication. The Impella RP was indicated to provide “temporary right ventricular support for up

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<sup>13</sup> An “infarct” is an area of dead tissue that can occur in the heart as a result of inadequate blood flow.

to 14 days in patients with a body surface area  $\geq 1.5 \text{ m}^2$  who develop acute right heart failure or decompensation following left ventricular assist device implantation, myocardial infarction, heart transplant or open-heart surgery.” As discussed in further detail below, the Impella RP’s narrow indication was a significant obstacle to Abiomed’s ability to convince hospitals and physicians to use the device, and thus a significant obstacle to the Company’s revenue growth.

## **2. Competition for the Impella Platform**

46. Prior to and throughout the Class Period, the IABP, first approved for use by the FDA back in 1976, was the biggest competition for the Impella Platform. The IABP is a therapeutic device that helps the heart pump more blood.<sup>14</sup> It consists of a long balloon attached to the end of a long, flexible tube called a catheter. The IABP is inserted percutaneously through the aorta, and is attached to a computer console that inflates and deflates the balloon as the heart beats. Similar to the pumps in the Impella Platform, the IABP provides temporary support to patients with heart trouble. Also similar to the pumps in the Impella Platform, the IABP has been approved by the FDA for use in PCI procedures, as well as for patients suffering from cardiogenic shock.

47. According to a December 2018 study, the IABP “has been the most widely used mechanical circulatory support device for decades, because of its inexpensiveness, ease of use, low rate of complications and rapidity of insertion in acute settings.”<sup>15</sup> Additionally, Defendants

<sup>14</sup> *Intra-Aortic Balloon Pump Therapy*, JOHNHOPKINSMEDICINE.COM, <https://www.hopkinsmedicine.org/health/treatment-tests-and-therapies/intra-aortic-balloon-pump-therapy>.

<sup>15</sup> Benoit Hellau, et al., *Current indications for the intra-aortic balloon pump: The CP-GARO registry*, in ARCHIVES OF CARDIOVASCULAR DISEASES (2018), <https://www.sciencedirect.com/science/article/pii/S187521361830086X#!>.

have acknowledged IABP as a competitor for the Impella Platform, noting in January 2018 that the IABP had been around for 40 years.

48. Despite repeated statements from Defendants about the IABP being the “old standard,” and more dangerous than Impella pumps, following the end of the Class Period, Defendant Minogue acknowledged in August 2019 that inotropes<sup>16</sup> and IABPs “continue to be first line of therapy.”

49. Moreover, as described in further detail below, the results of multiple observational studies released at the end of the Class Period showed the use of Impella pumps was associated with higher incidences of death and bleeding, and increased costs. However, an August 2, 2019 analyst report from *Guggenheim Securities* titled “ABMD – Lack of Recovery Suggests Deeper Issues; Downgrading to NEUTRAL,” estimated that there were still twice as many IABPs implanted than Impella pumps—contrary to Defendants’ assertions throughout the Class Period.

### **3. Abiomed’s Five Year Vision for Growth and Financial Revenue Outlook**

50. On August 11, 2015, Abiomed laid out the Company’s LRP which included specific figures for the Company’s revenue and operating margin goals. Defendant Minogue and other Abiomed executives informed investors that by August 2020, Abiomed was expecting annual Impella revenues between \$1.2 and \$1.8 billion, while also growing operating margin to more than 30%. The Company based these projections on: (1) assumptions about the size of the

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<sup>16</sup> Inotropes are agents (*i.e.*, drugs) that alter the force or energy of muscle contractions. Positive inotropes strengthen the force of the heartbeat, while negative inotropes weaken it. Positive inotropes can be used for patients suffering cardiogenic shock following cardiac surgery, and both types are sometimes used for patients who have suffered a heart attack. *Inotropic Agents*, TEXASHEART.ORG, <https://www.texasheart.org/heart-health/heart-information-center/topics/inotropic-agents/>.

available market for the Impella Platform; (2) the average selling price of the pumps; and (3) “the financial impact of unlocking new patient opportunities.”<sup>17</sup>

51. During the presentation of Abiomed’s LRP, Defendant Minogue informed investors that the potential market for the Impella Platform included 221,000 patients, with 121,000 Protected PCI patients and 100,000 patients suffering cardiogenic shock, and potential sales revenue of more than \$5 billion. Abiomed informed investors that the Company’s current growth showed that by FY20, the Company would have 21.5% market penetration within those 221,000 potential patients, for revenue from Impella sales of more than \$1.2 billion. However, Abiomed also informed investors that the Company was projecting a top range of up to 40% market penetration for revenue from Impella sales of more than \$1.8 billion.<sup>18</sup> Defendant Minogue also projected that Abiomed would grow its operating margin to more than 30%, approximately double the figure for FY16, while maintaining a gross margin of approximately 80%. These projections all assumed a decreasing average sales price for each of the pumps in the Impella Platform.<sup>19</sup>

52. An August 12, 2015, analyst report from *Raymond James* noted that Abiomed “laid out a large, underpenetrated Impella market opportunity.” That report stated that “the addressable market for percutaneous circulatory support is much bigger than we previously

<sup>17</sup> *Abiomed Outlines Long-Term Growth Strategy and Unveils Future Products at Annual Investor Conference*, ABIOMED.COM (Aug. 11, 2015), <http://investors.abiomed.com/news-releases/news-release-details/abiomed-outlines-long-term-growth-strategy-and-unveils-future>.

<sup>18</sup> As a part of the presentation, Abiomed also informed investors that the Company was projecting Impella RP to be in an average of 50 new sites a quarter by FY20.

<sup>19</sup> The LRP assumed an average sales price of just under \$20,000 for Impella pumps, while the average sales price is actually \$25,000. As discussed in further detail below, Abiomed fell well short of these revenue projection, and the fact that Abiomed underestimated the average sales price in the LRP meant that Abiomed sold even fewer Impella pumps than the impending revenue shortfall itself indicated.

thought.” That report also noted that “the company is spending aggressively to appropriately market and educate physicians (and patients) about the Impella technology.”

53. Analysts focused on these numbers well beyond August 2015, including during the Class Period. For example, on June 8, 2017, *William Blair* published an analyst report titled “Assuming Coverage With an Outperform Rating,” noted that Abiomed had to “dedicate meaningful resources to [the Impella expansion] effort to educate physicians and build Impella programs throughout the country.” That report also acknowledged the tension between Abiomed’s need to “dedicate meaningful resources” to Impella expansion, and the Company’s target of 30% operating margin. *William Blair* noted that Abiomed would need to “show leverage in SG&A [as a percentage of revenue] from 49% today down to 40% in fiscal 2021.” In other words, to hit the targets Abiomed promised to the market, Abiomed needed to invest “meaningful resources,” *i.e.*, money, to convince surgeons to use the pumps in the Impella Platform, while simultaneously driving down costs as a percentage revenue, and increasing profits.

54. Between August 2015 and January 2019, Abiomed posted year-on-year revenue growth of more than 25% for fifteen (15) consecutive quarters, or approximately 3.5 years, while expanding its quarterly operating margins from 20.0% to 29.2%.

55. But, by the start of the Class Period in May 2018, Abiomed’s growth was plateauing as its market penetration stagnated. Notwithstanding, Defendants still repeatedly assured the market as to the sustainability (and consistency) of the Company’s growth, and its opportunities for expanded use and adoption of the entire Impella Platform.

56. But the Company was ultimately forced to disclose at the end of the Class Period: (i) decelerating year-on-year growth of only 19% for 4Q19 ended March 31, 2019; and (ii) year-

on-year growth of just 15% for 1Q20 ended June 30, 2019 – a staggering slowdown in just two quarters. Moreover, by the start of 2018 Company had only achieved 9% penetration of a potential 231,000 patients, and only 11% by the start of 2019, approximately half of the bottom end of the projections from the LRP.

#### **4. Abiomed’s Issues with the FDA**

57. As noted above, the pumps in the Impella Platform are considered Class III devices by the FDA, and thus must receive PMA before the Company can market and sell the pumps. The PMA includes an indication that identifies patients for whom doctors can use the device. Abiomed had numerous issues with the FDA related to the safety and effectiveness of Impella pump during the Class Period. As discussed above, the FDA initially approved the Impella RP for marketing and sale under an HDE in January 2015. Under the HDE, the FDA approved the Impella RP for use in “in pediatric or adult patients who develop acute right heart failure or decompensation following left ventricular assist device implantation [“LVAD”], myocardial infarction, heart transplant, or open-heart surgery,” *i.e.*, patients with a lack of blood flow to the right side of their heart.<sup>20</sup>

58. The FDA issued its approval letter for the Impella RP on September 20, 2017. The Impella RP was approved for use under narrow circumstances. The Impella RP was “indicated for providing temporary right ventricular support for up to 14 days in patients with a body surface area  $\geq 1.5 \text{ m}^2$ , who develop acute right heart failure or decompensation following [LVAD] implantation, myocardial infarction, heart transplant, or open-heart surgery.”

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<sup>20</sup> *Abiomed Receives FDA HDE Approval for the Impella RP*, ABIOMED.COM (Jan. 27, 2015), <http://investors.abiomed.com/news-releases/news-release-details/abiomed-receives-fda-hde-approval-impella-rp>.

59. In that letter, the FDA also informed Abiomed that it would have to provide post-approval safety and effectiveness data to the FDA on patients “through 1 year post-Impella RP explant.” Abiomed was required to provide data on 60 consecutively treated patients, and perform analyses and provides results on the following outcomes: (1) survival rate at 30 days post-device explant or hospital discharge (whichever is longer), or to the start of longer term therapy; (2) bleeding, hemolysis, and pulmonary embolism at 30 days or discharge (whichever is longer); and (3) “device malfunction, central venous pressure, cardiac index, and [LVAD] flow.”

**(a) February 2019 FDA Letter to Healthcare Providers Regarding the Impella RP**

60. On February 4, 2019, letter to health care providers, the FDA noted that in Abiomed’s “premarket clinical studies, where strict inclusion and exclusion criteria were followed, a total of 44 out of 60 patients (73.3%) survived to 30 days post-device explant or hospital discharge (whichever is longer) or to the start of longer term therapy.” However, the FDA also stated that: “Interim results from the most recent PAS report, which reflect device use in a broader patient population, indicate that only 4 out of the 23 enrolled PAS patients (17.4 percent) met the primary survival endpoint.” In the PAS Study, though, 16 of the 23 patients enrolled would not have met the criteria for enrollment in the pre-market study because of their at-risk condition. Specifically, those patients in the post-approval study “were more likely than the premarket clinical study patients to have been in cardiogenic shock for longer than 48 hours, experienced an in-hospital cardiac arrest, been treated with an intra-aortic balloon pump, or suffered a pre-implant hypoxic or ischemic neurologic event.” The FDA advised that “physicians should be aware that the occurrence of one or more of these events prior to Impella RP implantation may decrease expected survival rate.”

61. On February 4, 2019, *TCTMD* published an article titled “FDA Warns Healthcare Providers of Potential Rise in Death Rate With Impella RP,” which noted that Abiomed acknowledged that to provide the purported benefits, the Impella RP must be used properly. On February 5, 2019, *Boston Business Journal* published an article titled “Abiomed investors wary after FDA warns of higher death rate for heart pump recipients,” which quoted from the FDA letter regarding using the Impella RP “for the currently approved indication in appropriately selected patients.”

**(b) May 2019 FDA Letter to Healthcare Providers Regarding the Impella RP**

62. In its May 21, 2019, update regarding the Impella RP,<sup>21</sup> the FDA noted that in the post-approval study, the survival rate of patients that would have qualified for the pre-market study was 64% while the survival rate among patients that would not have qualified was less than 11%. The FDA stated it believed that “when the device is used for the currently approved indication in appropriately selected patients the benefits of the Impella RP continue to outweigh the risks.” (emphasis added). Additionally: “In April 2019, the FDA approved revised labeling for Abiomed's Impella RP to include more information about patient selection and which patients may benefit the most from treatment with the device.”

63. This letter from the FDA made clear that the Impella RP should not be used for patients outside of the narrow indication it was approved for, and thus was not the growth driver that Abiomed claimed it would be. The two FDA letters (February and May 2019) had broader

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<sup>21</sup> *UPDATE: Increased Rate of Mortality in Patients Receiving Abiomed Impella RP System - Letter to Health Care Providers*, FDA.GOV (May 21, 2019), <https://www.fda.gov/medical-devices/letters-health-care-providers/update-increased-rate-mortality-patients-receiving-abiomed-impella-rp-system-letter-health-care>.

implications, as they validated concerns related to Abiomed's ability to convince doctors to use the Impella Platform over IABPs.

**(c) Abiomed Submitted a Misleading Patient Brochure on the Impella 2.5 to the FDA**

64. In February 2015, the FDA posted to its website a patient brochure made by Abiomed for the Impella 2.5. That brochure contained results from the PROTECT II trial, which compared the Impella 2.5 to the IABP.

65. Trial results can be reported as hierarchical or nonhierarchical. Hierarchical study results, which speak to ultimate efficacy but not really safety, only include the worst result, so if a patient needed CPR, had a stroke, and then died, only the death would be recorded as an adverse event. Nonhierarchical study results include all adverse events, so if a patient needed CPR, had a stroke, and then died, all three adverse events would be recorded.

66. On June 24, 2019, Dr. Boback Ziaeian<sup>22</sup> posted a thread on Twitter detailing the misleading study results. In the Impella 2.5 patient brochure, which Abiomed submitted to the FDA and the FDA posted to its website, Abiomed reported results from the PROTECT II trial using hierarchical data for the Impella 2.5, but used nonhierarchical data for the IABP in the same table without indicating that vital difference. This created a skewed comparison which made the Impella 2.5 look better relative to the IABP than was actually the case.

67. On June 25, 2019, Abiomed responded to Dr. Ziaeian's thread, and admitted the data was incorrect. The FDA's website was subsequently updated with the correct information, which showed significantly higher incidences of heart attack, a need to repeat the procedure,

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<sup>22</sup> Dr. Ziaeian is an Assistant Professor of Medicine at the David Geffen School of Medicine at UCLA in the Division of Cardiology. His primary research interests are in cardiovascular outcomes research, disparities in cardiovascular care, cost-effectiveness, and the quality of heart failure management.

sudden kidney failure, and patients requiring CPR or electrical shock to restore a normal heartbeat.

**B. Confidential Witnesses**

68. Former Abiomed employees: (i) confirm that the market for Impella pumps was saturated by the start of the Class Period, and (ii) provide factual support for a strong inference of scienter on Defendants' part regarding the false and misleading nature of their statements and omissions during the Class Period.

69. CW-1 was a former Cardiology Account Manager at Abiomed on the West Coast for the entire Class Period. CW-1 reported to a manager who reported to Jen Weddell (West Region Director of Sales) who reported directly to Michael G. Howley (Vice President and General Manager of Global Sales at Abiomed).

70. CW-2 worked at Abiomed in numerous clinical roles from October 2014 until May 2020, and most recently served as a Senior Clinical Consultant in Florida from April 2018 to May 2020.

71. CW-3 was a former Commercial Training Consultant (Global) at Abiomed from January 2017 to May 2019. CW-3 reported that he was responsible for aligning Abiomed's commercial initiatives with its sales progress and was brought in by Abiomed to launch commercial training processes for their sales methodology. CW-3 reported to the marketing department and often interacted with Abiomed's executives, including the CEO, Chief Commercial Operations Officer, VP of Sales, VP of Marketing, and sales leaders, directors, and representatives.

72. CW-4 was a former Cardiology Account Manager for Abiomed in the Miami, Florida area from January 2019 to January 2020. In his role as a sales representative, CW-4

managed Abiomed's Impella products. CW-4 worked with up to four clinical specialists at any given time who supported him in his role as a CAM.

73. CW-5 was a former Clinical Consultant for Abiomed on the East Coast from prior to the Class Period through the Spring of 2019.

74. CW-6 was a former Logistics Specialist and, before that, a Production Associate at Abiomed's Headquarters in Danvers, Massachusetts from October 2017 to September 2019. CW-6's responsibilities included warehouse and inventory management, including preparing periodic reports in these areas.

75. CW-7 was a former Regional Clinical Manager at Abiomed from April 2019 to December 2019 and has 21 years of industry experience. CW-7 was in charge of a clinical sales team which consisted of approximately 10 members and was responsible for Ohio and Indiana, along with a part of Kentucky. CW-7 reported to a Regional Sales Director at Abiomed, who in turn reported to a Zone Manager, who each reported to Mike Howley, who reported to Defendant Minogue.

### **1. Impella Sales**

76. CW-2 advised that when a hospital made its first Impella purchase, it was required to purchase a minimum of three Impella devices. CW-2 added that Abiomed encouraged hospitals to maintain at least two Impella devices "on the shelf," although this was not a requirement. CW-1 corroborated that Abiomed strongly recommended that its hospitals and doctors carry two of each Impella device. Indeed, CW-2 confirmed that "95%" of hospitals kept two or more devices on hand at all times, while smaller hospitals did not, due to the less frequent use.

77. CW-2 stated that while some Abiomed sales representatives would encourage locations to keep two devices on hand after their initial purchase of three, he did not do this. In

CW-2's opinion, this could damage long-term relationships once Impella products expired (due to infrequency of use) and the hospitals began losing money.<sup>23</sup> According to CW-2, eventually representatives lost accounts as unused devices expired. CW-2 explained that the majority of accounts used at least one Impella per year, but smaller hospitals that used devices less often were the ones hesitant to maintain two devices in inventory.

78. CW-2 noted that Centers for Medicare and Medicaid Services ("CMS") determined the reimbursement levels for Impella every one or two years and that the device, as a LVAD (left ventricular assist device) garnered a reimbursement of approximately \$70,000. According to CW-2, every patient who checks into a hospital receives a diagnosis related group ("DRG") code that corresponds with a certain dollar value and when it came to the Impella, a certain reimbursement rate was triggered when a doctor noted that it was used. CW-2 advised that hospitals would receive reimbursement if the product was placed in a patient with insurance. However, if the device expired and was not used in a patient, then the hospitals would not be compensated at all. CW-2 explained that this is why, if a representative misled a client into purchasing more Impella devices than they needed, that there could be long-term ramifications for the relationship with the client.

79. In regards to the 30% year-on-year growth figure touted by Abiomed management, CW-7 said that management "talked about it all the time." CW-7 advised that due to the pressure to achieve growth goals, sales representatives felt pressured to sell "more than necessary." CW-7 explained that this meant selling more pumps to hospitals than the sales representatives thought they could realistically use, and potentially damaging long-term relationships with those hospitals in the process.

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<sup>23</sup> According to CW-2, all Impella products have a shelf-life of 20 months.

80. CW-1 recounted that during his tenure at Abiomed, CAM's sales goals were always aggressive and unattainable. According to CW-1, the sales directives for Abiomed's CAMs came from Mike Howley (Vice President and General Manager of Global Sales) through Howley's managers.

81. CW-3 recalled that the turnover, or churn, for CAM employees at Abiomed was very high as they worked 24 hours a day, 7 days a week. According to CW-3, Regional Clinical Managers ("RCMs") who were responsible for supervising the Clinical Consultants and purportedly lessening the CAM's workload created an additional disconnect between Abiomed's CAMs and Clinical Consultants. According to CW-3, clinical employees had medical backgrounds and were very technical and patient and process oriented, while sales employees were focused on driving large deals, getting equipment into hospitals, and negotiating contracts.

82. According to CW-1, at the end of each quarter, Abiomed would try to push hospitals to submit a purchase order that could be charged by Abiomed upon product shipment, so the Company could record the sale in that quarter's earnings.

83. CW-2 reported that, at the end of a quarter, Abiomed sales representatives would offer hospitals a free console (power source) if they purchased two catheters,<sup>24</sup> which would occur approximately two or three quarters a year with a particular focus on larger hospitals. CW-2 explained that Abiomed did not have these promotions when he first started at the Company, but that their use increased during his tenure. CW-2 added that often if a hospital needed a console that they would be receptive to these types of promotions because the catheters earned them a reimbursement, whereas the purchase of a console was a capital cost and not

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<sup>24</sup> A catheter is a flexible, hollow tube designed for insertion into passageways to drain fluids or distend body passages. In Impella devices, the catheter connects the blood inlet area to the blood outlet area, and allows for blood to flow between different areas of the heart.

reimbursable for the hospital. CW-2 explained that representatives would offer these deals when hospitals expressed a need for a console in order to increase their sales numbers.

**2. Questions About the Impella Clinical Data and the Accuracy of its FDA Reporting**

84. CW-2 explained that the February 2019 FDA letter regarding the increased mortality rates for the Impella RP led to a “small” impact on sales, not a significant impact. CW-2 explained that the impact of that FDA letter was mitigated when the FDA issued a follow-up letter in May 2019 to explain that an increased mortality rate was being observed because doctors were using the RP as a “last ditch effort” when it was already too late for a patient to be saved.

85. According to CW-1, most decisions at the Company were made in order to drive up the Company’s stock price. CW-1 noted that Abiomed presented an appearance of being people and customer-focused, but the reality was that that was not true. CW-1 explained that when doctors or hospitals asked Abiomed for research assistance, Abiomed would deny such assistance if it cost them money. CW-1 gave the example of doctors who wanted to do research on Abiomed’s Impella products. According to CW-1, if the requesting doctor wasn’t a high-volume user or “high-end,” Abiomed would not allow the doctor to conduct the research they requested. In addition, according to CW-1, Abiomed was more inclined to provide assistance to doctors who pushed Abiomed’s “message” over doctors who did not promote the Company as much.

86. CW-1 confirmed that doctors often questioned Abiomed’s products, including when to use them, who collected data on the product, and the substance of the data that was collected. CW-1 recounted how Abiomed pushed its own data on doctors and “shamed” them

into using their devices, and therefore, doctors had a negative perception of the Company and viewed Abiomed as a “bully.”

87. According to CW-1, the data Abiomed provided to the FDA on its products was collected by the Company, which some doctors believe may be skewed. CW-1 reiterated that Abiomed is not willing to help doctors perform research because the Company could be at risk if a trial is run and the data came out negative. CW-1 added that the perceived adoption curve for the Impella devices by the Company’s CEO and executives is skewed and was likely what was contributing to Abiomed’s lack of growth.

88. According to CW-1, a lot of doctors are not comfortable using the Impella devices due to the high complication rates of implanting them in patients. CW-1 gave the example how Abiomed would dissuade hospitals and doctors from reporting groin complications.

89. CW-1 explained that Abiomed’s Impella products had strict and clear indications for when they could be used. CW-1 stated that the Company’s Protected Percutaneous Coronary Intervention (“PCI”) coordinators were in a bit of a gray area as the PCI Coordinators were trained by Abiomed and employed by the hospitals, and were intended to focus primarily on making Impella sales.

90. CW-4 explained that hospitals and doctors faced many challenges with Impella products despite its life-saving capabilities, explaining that the device costs \$25,000 and is disposable with an expiration date. According to CW-4, if an Impella device was implanted in a patient’s heart, a very large hole needed to be made in the patient’s leg for implantation, which had very high complication rates. In addition, patients who were implanted with Impella products needed monitoring for a long period of time to ensure that the implant worked properly and there were no complications.

91. According to CW-3, there was a divide among doctors' opinions on using Impella products. CW-3 recalled that many doctors were concerned about the large porthole that was required to be made in patients for implantation because it led to a high potential for bleeding complications. CW-3 added that many doctors were not trained to use Impella devices and were already trained to help patients in other ways. CW-3 recalled that he worked with PCI Coordinators who were employees of hospitals whose responsibilities were to coordinate with care physicians and other service lines to assess whether patients needed procedures, and speed up and streamline cases.

92. Additionally, CW-3 said he took hundreds of field rides with representatives and he reported sales trends and training gaps to Abiomed's Senior Director of Operations and the Company's VP of Sales.

### **3. Market Saturation of Impella/Abiomed's Growth Rate Stalls**

93. CW-1 recalled how Abiomed expected their sales team to increase sales 30% quarter-over-quarter which was relayed by Abiomed to Wall Street. CW-1 also recalled that Abiomed over-promised to investors that the Company expected to experience 30% growth quarter-over-quarter, which was not realistic. CW-1 stated that sales quotas were hardly ever attained by Abiomed employees.

94. According to CW-1, at the end of each quarter, regardless of whether or not he met his quota, he received messages from his clinical manager, asking him where he could increase his numbers. CW-1 advised that Clinical Managers would check each of the hospitals in his territory to see where he could increase device sales. CW-1 was responsible for replying to his Clinical Manager with explanations of which hospitals could and could not add Impella devices to their shelves.

95. CW-5 recounted how sales goals increased 30% quarter-to-quarter which CW-5 described as unheard of in the medical field. CW-5 explained that clinical consultants required a strong clinical background and were often relied on to ensure proper patient care. CW-5 recounted how he was responsible for helping with the sickest of patients while Abiomed was simultaneously pressuring him to make sales, which made the job more challenging. CW-5 added that Abiomed put a lot of pressure on the teams to increase sales numbers and that sales representatives felt that pressure the most.

96. CW-5 recalled there was universal pressure from the Company for employees to meet their sales goals. CW-5 explained that this sales pressure was applied to all employees without taking into account exigent circumstances in various areas that might affect the attitudes of hospitals and doctors towards Impella pumps and make sales more difficult.

97. Regarding Abiomed's explanation that its sales were negatively impacted by market noise after the February 2019 FDA letter, CW-5 noted that he sold more Impella RP devices after the FDA notice was issued. CW-5 explained that prior to the FDA's notice, doctors were using RPs when it was too late for the patient. According to CW-5, doctors were not looking for issues that could be corrected earlier by the Impella RP device which they learned from the February 2019 FDA notice.

98. CW-3 recounted that during his time at the Company, people at Abiomed often discussed the Company's growth and initiatives to improve performance. CW-3 recalled that discussions of growth and initiatives happened on "all-field" calls (discussed below). During his time at Abiomed, CW-3 ran "cause analyses" on Abiomed's performance in order to identify the cause of the declines in the Company's sales. As a result of those cause analyses, CW-3 ascertained that there was a clear disconnect between Abiomed's Clinical Educators or

Consultants and their Cardiology Account Managers. CW-3 explained that Clinical Consultants were nurses or care practitioners with experience in the cardiac space. According to CW-3, while CAMs were Abiomed employees with medical device sales experience, Clinical Consultants, who were approximately 75% of Abiomed's salesforce, did not have sales experience. According to CW-3, Abiomed needed CAMs to make sales in order for the Company to earn revenue.

99. CW-2 confirmed that the Company's expectation of achieving 30% growth each year was "harped on" early in his tenure when it was more achievable, but as his time with Abiomed continued, the 30% growth rate became more of an unachievable goal. CW-2 explained that "all of a sudden," around the time that the "stock took a deep dive,"<sup>25</sup> the 30% growth rate goal was no longer within reach as Abiomed had "maxed out" all the possible hospital clients who could purchase its devices. CW-2 added that there was only one remaining hospital in his territory that did not yet carry any Impella products.

100. CW-2 explained that there was no room for additional market penetration for Impella and the only way to continue the Company's growth was to increase usage among existing hospitals. CW-2 added that Abiomed's consultants would go back to doctors and educate them on expanded uses for Impella products. According to CW-2, some doctors were hesitant to increase Impella usage - usually as a result of their age, or if they had had a negative experience with an Impella product in the past. CW-2 advised that in order to achieve growth, it was important to find a doctor to "champion" the Impella products in order to try to convince other doctors to join them, and also to get the device into the hospital in the first place.

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<sup>25</sup> Abiomed's share price reached a record high at closing of \$449.75 per share on September 28, 2018, before falling more than \$150 over the next approximately two months.

However, CW-2 explained that the device is “not for everybody” and the 14-inch French sheath<sup>26</sup> “scared off” some doctors. CW-2 said that when he first began working for Abiomed that hospitals may have failed to reorder simply because they were not using the device, but that more recently the reasons would often either be that the hospital had enough product on its shelves or that it had hit its limit for inventory expenditures and had to wait until the next period.

101. CW-4 reported that soon after he started at Abiomed in January 2019, he realized sales goals were very challenging. CW-4 explained that when he joined the Company in January 2019, 95% of accounts already had Impella products on the shelves. According to CW-4, the sales goals were discussed internally between himself and other sales representatives that Abiomed would only reach one third of its sales goals quarter over quarter. CW-4 explained that reports on sales were generated using Abiomed’s CRM Salesforce, a web-based application system that contained all of Abiomed’s data on sales figures in all territories. According to CW-4, Abiomed incentivized employees to reach sales goals by offering a \$60,000 to \$70,000 quarterly bonus for hitting their exact quotas.

102. CW-4 noted that he joined Abiomed after the Company had its “growth boom” when the Impella products first came on to the market. CW-4 advised that Abiomed experienced rapid growth then as they adopted new accounts (hospitals and doctors) who were interested in making first time purchases of the devices. When CW-4 started at Abiomed in January 2019, every hospital in his territory already had Impella devices on their shelves. CW-4 explained that growth was most rapid for the initial sales of products rather than with re-orders. CW-4 gave the example that his territory could have initially sold 1,000 units, but could have only sold 50 on re-

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<sup>26</sup> Catheters are sized by what are called “French sizes” or “Fr.” The French size refers to the diameter of the tube and catheters range from 5 Fr to 24 Fr.

order. CW-4 explained that the initial purchase of a \$25,000 item significantly drove up Abiomed's revenues but re-order relied on use of the device. CW-4 explained that with their first purchase, a hospital may purchase two to four Impella products, and that additional sales relied on hospitals' use of their initial order. However, CW-4 said that training and implantation did not "catch up" with the volume of product that was initially ordered by hospitals, and therefore reorder volume was less than the initial sales volume.

103. CW-4 reported that a lot of factors contributed to a hospital or doctor not wanting to reorder more Impella devices. CW-4 recounted that the expectation of how many patients needed the device lessened over time and that there was a significant number of patients that the device should have been used for, but doctors only used the device on 10-to-15% of those patients. CW-4 explained that the complications with using Impella devices and management of patients post-procedure made doctors very uncomfortable.

104. CW-6 confirmed that Abiomed's growth slowed down during his tenure. According to CW-6, when he worked in production (October 2017 – April 2018), some days he worked 12 hours, including overtime, and on other days he could barely find things to do to fill his 8-hour work day. .

105. When CW-6 was a Logistics Specialist (May 2018- September 2019), he noticed Abiomed shipping out fewer products each quarter. Indeed, CW-6 said that during the last quarter he worked at Abiomed, there were not a lot of orders to ship. CW-6 gave the example that during the first quarter that he worked as a Logistics Specialist (Q1 FY19), Abiomed was very busy and shipped out 500 pumps, however, during Q2 FY19, they only shipped out 200 pumps, and during Q3 FY19, they only shipped out 100 pumps. According to CW-6, Abiomed most often shipped out the Impella CP pump.

106. According to CW-6, Abiomed employees often spoke about the decline in Abiomed's growth. CW-6 opined that Abiomed's growth may have slowed down for many reasons including increased competition, low use by doctors, and poor engineering and production by intern engineers who were very young and had little to no experience. According to CW-6, the growth decline at Abiomed started during Abiomed's fourth quarter in 2018 and first quarter of 2019.

107. CW-7 advised that when he started at Abiomed in April 2019, Abiomed had unrealistic growth expectations. CW-7 explained that upper management, including VP and GM of Global Sales and Marketing Michael Howley, at the Company pushed their desire to achieve their goal of 30% growth and no matter what numbers the staff produced, it was "never enough." CW-7 recalled receiving emails from Howley that would either be directed to the national group, or more specifically to his region. CW-7 added that those regional emails included all sales regional activity. According to CW-7, the growth potential for the sector was hindered by the limited market and lack of alternative uses for Impella products. Thus, sales goals were not achievable.

108. According to CW-7, Impella sales slowed during his tenure (April 2019 – December 2019) - more specifically utilization slowed. CW-7 explained that doctors were looking at alternatives to Impella products, most notably the use of IABP (balloon pumps) because they cost only a few hundred dollars in comparison to the approximately \$25,000 price tag of Impella products. CW-7 advised that some doctors were electing not to use either balloon pumps or Impella products and that some doctors would look for an excuse not to use Impella products.

109. CW-7 explained that some hospitals were wary of the cost of Impella products while some doctors were concerned about the budget ramifications for them personally. CW-7 stated that doctors could face pressure from colleagues or superiors for routinely using such an expensive device, and others faced government investigations to determine the validity of their usage. CW-7 explained that it was a regular occurrence for doctors to voice these concerns. According to CW-7, many doctors also are hesitant to use Impella products due to implantation in the groin because that area is highly susceptible to complications.

110. CW-7 explained when it came to sales at Abiomed, what was most important were new accounts and utilizations. CW-7 noted that the new account numbers were fine, but the difficulty came from “pull through rate” or utilization. CW-7 explained that new accounts required a purchase of three devices with the expectation that hospitals would keep “two on the shelf” going forward after use of one device.

111. CW-7 explained that by the time he joined Abiomed in April 2019, the Company could no longer “rely on heart attacks” for utilization and there was a need to push for usage in high risk PCI (percutaneous coronary intervention) patients. CW-7 noted that this could be difficult because in those circumstances, the Impella served as protection, increasing the probability of a successful operation, but was not absolutely necessary. CW-7 recalled his territory having a single Protected PCI Coordinator and it was his job to identify high risk patients and coordinate with the cardiology group regarding why a patient would be a good candidate for an Impella. CW-7 explained that the intention was to drive utilization; however, a good PCI Coordinator can have a positive impact, while a poor one could hurt utilization numbers.

#### **4. Meetings and Reports**

112. According to CW-1, Michael G. Howley, Vice President and General Manager of Global Sales at Abiomed, held monthly sales calls for all CAMs in the United States where Howley presented information regarding device data and overall sales and outcomes, which according to CW-1, were often inaccurate.

113. According to CW-7, he had weekly meetings to discuss sales numbers and utilization with his region and monthly conference calls with managers from all territories. CW-7 noted that he spoke daily with his team regarding performance numbers.

114. Regarding utilization, CW-7 advised that “everything is tracked” through Salesforce and that he was able to see every patient in his territory from his phone or laptop. CW-1 also reported that Abiomed tracked device purchases and implantations using a Salesforce tool. CW-1 stated that when a product was implanted, hospital staff recorded who worked on the case and the patient’s outcome.

115. CW-7 explained that when a device is plugged in to the power supply, Abiomed had access to all pertinent data and they knew what exact products were being used. CW-7 added that Abiomed leadership was able to access device data from anywhere in the world. CW-7 also explained that the process was “micro managed” and it was important to know what, how many, and where products were being used.

116. According to CW-4, reports on sales were generated using Abiomed’s CRM Salesforce, a web-based application system that contained all of Abiomed’s data on sales figures in all territories. CW-4 confirmed that Salesforce reports were automatically generated and sent to each sales representative on a daily basis and were also available to high level executives. CW-4 referred to these reports as “layered” depending on which territories the person oversaw, meaning that each layer of management got reports on the territory they were responsible for.

117. CW-2 corroborated that every case was logged into Salesforce and Abiomed was aware when a device is used, and in turn, was aware of when a hospital should be re-ordering. According to CW-2, a “Re-Order Report” was generated by the Company’s CRM Salesforce and detailed the number of cases that week and whether re-orders had occurred. CW-2 explained that this report was provided to directors at least weekly who could then bring it up the chain of command.

118. In reference to Abiomed’s use of Salesforce, CW-3 recalled that he created an app within Abiomed’s Salesforce app that served as a sales funnel and tracked potential patients, implanted patients, and explanted patients. CW-3 explained that Salesforce was used as a medical database to record patient outcomes or the full context of a patient’s “story.”

119. CW-6 reported that Abiomed held “All-Hands” Meetings every quarter where the Director of Manufacturing talked about the decline in growth, which CW-6 said started in the fourth quarter of 2018 or first quarter of 2019. CW-7 advised that Howley and Defendant Minogue would speak at the “All-Hands” Meetings.

120. CW-7 described Defendant Minogue as “very hands on” and recalled how it was not uncommon for him to send e-mails or texts late in the day asking relatively obscure questions, such as what were a particular employee’s top ten takeaways from a recent study.

121. CW-7 reported that Defendant Minogue “had access to everything we all had access to,” and that he was “definitely very well-informed,” as to the performance of the Company.

122. According to CW-3, discussions of growth and initiatives happened on Monthly “All Field” Calls. CW-3 explained that Abiomed’s CEO (Defendant Minogue), COO (David Weber), CCO, Marketing VPs, and Sales Director VPs all participated on the All Field calls,

which he referred to as “Visibility Calls,” where what was currently going on and what was coming, such as strategic initiatives or product launches, at Abiomed were discussed. CW-3 said that during these calls, slide decks were used to discuss meeting points, and that Defendant Minogue sometimes used some of the slides in advisory board meetings. CW-3 explained that the advisory board consisted of research investigators and other people in leadership roles at Abiomed, adding that it was a mix of Abiomed employees and external people. CW-3 added that the advisory board would change depending on the project Abiomed was working on.

123. CW-3 confirmed that Mike Howley, VP of Sales, knew of every one of Abiomed’s accounts, doctors, and representatives and had “constant” meetings with Abiomed’s CEO, Defendant Minogue.

## **V. DEFENDANTS’ MATERIALLY FALSE AND MISLEADING STATEMENTS AND OMISSIONS DURING THE CLASS PERIOD**

### **A. Overview of Defendants’ Fraudulent Conduct**

124. Lead Plaintiff alleges that the statements highlighted in ***bold and italics*** within this section were materially false and misleading because, among other reasons, they omitted to disclose material information of which Defendants were aware or were reckless in not knowing. As alleged herein, such statements artificially inflated or artificially maintained the price of Abiomed securities and operated as a fraud or deceit on all persons and entities that purchased or otherwise acquired those securities during the Class Period. Because Defendants chose to speak on the issues described below, it was important that they not mislead investors or withhold material information. As described below, Defendants created an impression of a state of affairs at Abiomed that differed in a material way from the one that actually existed.

**B. Defendants' Materially False and Misleading Statements and Omissions**

**1. Fourth Fiscal Quarter and Full Year 2018 Results - May 3, 2018**

125. On May 3, 2018, Abiomed issued a press release, attached to a Form 8-K signed by Defendant Trapp, reporting the Company's financial results for its fourth fiscal quarter and full year 2018 ended March 31, 2018. The press release reported quarterly revenue of \$174 million, up 40% year-over-year, and yearly revenue of \$594 million, up 33% year-over-year.

126. That same day, the Company hosted a conference call to discuss its quarterly Q4 2018 and annual FY 2018 results. During this call, Defendants lauded the Company's financial results, as well as its commitment to "*sustainable growth*." Defendant Minogue stated:

*And we're also maintaining this best in growth rate at a higher base and we're doing it while improving operating margin. So again, it's sustainable growth it's strategic, but we have to continue to improve outcomes and go at the right pace to have that -- the success we want, which is to achieve the best outcomes for patients.*<sup>27</sup>

127. As to the Company's revenue guidance, Defendant Trapp stated:

*The guidance is based on the following assumptions: continued penetration of the existing and expanded markets for Protected PCI in cardiogenic shock; accelerated growth in Impella RP post-PMA approval and approximately \$10 million in revenue from Japan. The business continues to expand rapidly, and our growth rates are in line with our 5-year vision outlined back in 2015. We will continue with our patients-first sustainable growth model.*

128. On the call, Defendant Minogue touted the increased adoption of the Impella RP, stating in pertinent part:

*Impella RP also delivered solid results in our second full quarter since the commercial launch with 48 new U.S. sites and growth of 93% in patients and 154% in revenue. However, Impella adoption is a function of training, data and time. And as a result,*

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<sup>27</sup> Unless otherwise noted, emphasis is added throughout this section.

*we are still in the early innings with a penetration rate of approximately 9% of 231,000 patients in the U.S. alone.*

\* \* \*

From a CMS population perspective, most patients above 65 years old are not candidates for heart transplant and prioritize heart recovery above all other treatment options based on quality of life and cost. *We believe our continued focus on best practice protocols are driving improved clinical outcomes and adoption.*

\* \* \*

In the RP we're only 19% penetrated in the install base. *So we have essentially, many years ahead of new doctors, new indications and new products into all the existing U.S. hospitals in our current install base.*

129. On the call, Defendant Trapp touted the expanded use of the entire Impella Platform, and the Impella RP specifically, stating in pertinent part:

In the U.S., at the end of fiscal year 2018, the Impella 2.5 and the Impella CP have been placed at 1,197 and 1,172 sites of the targeted 1,400 hospitals. Additionally, the Impella 5.0 and the Impella RP are currently at 516 and 270 sites, respectfully. *Both the 5.0 and RP are now being adopted by more sites and have significant runway.*

\* \* \*

*We saw broad-based growth in both the U.S. and outside the U.S. due to continued adoption of the entire Impella platform.*

\* \* \*

*We are replacing technology that's been around for 40 years, and we're going for the global standard of care.*

130. Also on the call, Defendant Minogue touted the Impella Platform's expanded approval from the FDA, stating in pertinent part:

*While we remain focused on the 231,000 U.S high-risk patient population, we acknowledge that these additional indications expand our addressable market and enable a wider range of patients in the future.*

\* \* \*

The patient population, if there are already surgical turndown and they have everything I described about comorbidities or complex anatomy or severe coronary disease, they don't have the option to go to surgery if something goes wrong. And we do think it will have an impact, and I think it will have an impact also in identifying patients that just do better with hemodynamic support. So it allows them to do longer inflations, potentially atherectomy, potentially reduce acute kidney injury, so we do think it will have an impact, and we're watching it as it goes out and it takes time for this information to filter.

131. On May 3, 2018, Chris Pasquale of *Guggenheim Securities* issued a Flash Note on Abiomed titled "ABMD - Growth Accelerates Driven by Shock and RP; FY19 Guidance Above the Street." In the report, Pasquale reported the following on the Company's Q4 2018 results:

**Abiomed announced strong fiscal 4Q18 results earlier this morning**, with revenues of \$174.4M (+40% YOY) coming in \$10.1M above consensus driven by strong Impella growth internationally and solid momentum in both the U.S. protected PCI (+26%) and cardiogenic shock indications (+43%). On the bottom line, EPS of \$0.80 (+141%) came in a full \$0.14 above consensus due in part to a lower than expected tax rate (24.0% vs. Street at 32.8%), which added \$0.09 to earnings. Even without this benefit, however, earnings would still have grown 113% YOY driven by impressive top line growth and margin leverage, as Abiomed's 4Q operating margin of 27.3% expanded 400bps YOY.

**Another year of strong growth on tap in FY19.** For fiscal 2019, management is guiding to sales of \$740-770M (+25-30%) compared to the current consensus of \$747M. Given the current momentum in the business, we believe this outlook could prove conservative. However, we view this range as striking the right balance between acknowledging this momentum and management's desire to keep a leash on Street expectations. And we would note that FY18 revenues finished 5% above the midpoint of the company's original guidance. Factors that we believe could drive upside as we move through the year include the continued Japanese rollout, ramping RP utilization, and growing adoption of shock protocols recommending early mechanical circulatory support as a result of the National CSI program.

**Strong quarter for U.S. Impella, driven by solid growth from both indications.** Domestic Impella sales rose 35% to \$146.2M, \$7.5M above consensus. Protected PCI volumes grew 26% in the quarter, while growth within the shock indication also remains strong at 43%. While we expect some quarter-to-quarter volatility between Impella's two main indications going forward, we see each as significantly under penetrated at this stage and would encourage investors to focus more on overall volume as an indicator of Abiomed's trajectory. Finally, the number of U.S. patients treated with Impella rose 35% to over 5,500.

132. On May 3, 2018, Jayson Bedford of *Raymond James* issued an analyst report on Abiomed titled “Abiomed - Momentum Building With Visible Upside Drivers; Outperform (\$365 PT).” In the report, Bedford reported the following on the Company’s Q4 2018 results:

**Recommendation:** F4Q revenue was 6% above consensus and growth accelerated to 40% y/y (from +30% for most of the year). In our opinion, this was a break-out quarter and Abiomed gained significant momentum heading into FY19. The initial FY19 guidance (25-30% y/y) bracketed consensus, but we expect this guidance to prove conservative (like it has for the last four years). While the valuation is not for everyone, Abiomed is the fastest growing mid/large cap med device company and with 28-30% operating margins (FY19 guidance), \$400M in net cash, and a pipeline of new products/indications, the story remains compelling. With visibility into upwards revenue revisions, we remain at Outperform.

133. On May 3, 2018, Raj Denhoy of *Jefferies* issued an analyst report on Abiomed titled “Abiomed (ABMD) - No End in Sight; PT to \$400.” In the report, Denhoy reported the following on the Company’s Q4 2018 results:

### **Key Takeaway**

ABMD posted a very strong Q with US Impella growing 35% and OUS 107%, handily beating our forecasts. Impella remains less than 10% penetrated of the current indications and potential new indications could expand the US opportunity further; international adoption is even lower. A growing body of clinical data, established and supportive reimbursement, and no competition add to the cleanest growth story in medtech. PT to \$400.

\* \* \*

**Raising PT to \$400.** ABMD remains the cleanest growth story in medtech. With its core Shock and PCI markets still grossly underpenetrated, well established clinical rationale for use, supportive reimbursement and economics, expanding pipeline (ECP, 5.5, BTR), new indications (STEMI), new geographic markets (Germany, Japan), and little competition, ABMD has a clear runway for continued outsized performance.

134. On May 24, 2018, Defendants filed Abiomed's Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fourth fiscal quarter and full year 2018 (the "2018 10-K"). Defendants Minogue and Trapp certified this filing.

135. The 2018 10-K reported:

*Our strategic focus and the driver of our revenue growth is the market penetration of our family of Impella heart pumps.* The Impella device portfolio, which includes the Impella 2.5, Impella CP, Impella RP, Impella LD and Impella 5.0 devices, has supported numerous patients worldwide. All of our product and service revenue in the near future will be from our Impella devices.

136. The statements referenced in ¶¶126-30 and 135 were materially false and misleading because Defendants failed to disclose material adverse facts about the Company's business. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that:

- (a) The Company's growth rate was stalling because Impella had reached market penetration – *i.e.*, most hospitals and facilities already stocked Impella products which were used infrequently and rarely required reorder;
- (b) The Company could not convince doctors to regularly use the Impella pumps over the IABP, or beyond its narrow indications; thus Abiomed could not achieve

significantly greater market penetration or sustain the growth rates the market had become accustomed to from the Company;

(c) Abiomed's revenue growth began to stall as early as May 2018, or Q1 2019, a trend which worsened during the Class Period;

(d) The growth expectations that Abiomed communicated internally to its sales employees and to the market were unattainable, in part, because hospitals were reluctant to stock extra Impella devices in their inventory and doctors remained reluctant to use Impella;

(e) The Company did not have a sufficient plan in place to stem its declining revenue growth; and

(f) Because the Company carefully tracked patient outcomes and sales (including sales results by territory and through Re-Order Reports) and the Individual Defendants participated in meetings and calls, and had access to such sales reports, they knew or recklessly disregarded the deceleration in revenue growth.

(g) Consequently, Defendants' statements during the Class Period regarding the sustainability of the Company's growth and expanded adoption and use of the Impella Platform were materially false and misleading at all relevant times.

## **2. First Fiscal Quarter 2019 Results – July 26, 2018**

137. On July 26, 2018, Abiomed issued a press release, attached to a Form 8-K signed by Defendant Trapp, reporting the Company's financial results for its first fiscal quarter 2019 ended June 30, 2018, and reporting revenue of \$132.5 million, up 36% year-over-year. In the accompanying press release, Defendant Minogue stated: "***Abiomed is committed to sustainable growth and improving patient outcomes each quarter. We do this through advanced training, product enhancements and sharing of best practices derived from real world experience.***"

138. That same day, the Company hosted a conference call to discuss its quarterly results for Q1 2019. During this call, Defendant Minogue touted that the Impella RP devices were now being used at 320 sites, and that the Company expected “***to see continued demand for the 5.0 and RP in the coming quarters.***” In response to analysts questions on the Impella RP, Defendant Minogue stated that the device was in “full launch mode,” and stressed the importance of having clearly defined usage protocols, stating in pertinent part:

***For the RP, we are in more of a full launch mode. We're continuing now to add 40 to 50 centers a quarter.*** We are learning things on the product itself, but remember it has multiple types of patients. So, some patients are failed transplant. Some are having biventricular shocks. Some are having RV infarcts. And so, it always comes back to having a protocol, making sure we have a heart team approach and make sure the device is put in timely.

139. Also on the call, Defendants touted the Company’s growth, and its efforts to maintain that growth, with Defendant Minogue stating in pertinent part:

In Q1, we delivered another record in revenue of \$180 million, up 36% versus prior year. ***U.S. patient utilization increased by 30% and was driven by Impella adoption in the Protected PCI and cardiogenic shock indications, which grew 24% and 37%, respectively.***

\* \* \*

***We have maintained our disciplined execution on our strategic goals and increased manufacturing capacity while expanding Impella adoption with new products, new indications and new geographies.***

\* \* \*

We believe our focus and investment on training will translate to increased Impella adoption and improved patient outcomes.

\* \* \*

***However, we're still in the early stages of educating and training everyone on these new indications, and we do expect to see more of these patients to continue to grow for the next couple of years.***

140. Defendant Trapp similarly touted the Company's revenue growth and the expansion of the Impella Platform, stating in pertinent part:

***Our platform of Impella products gives us the ability to make efficient investments in technology, which will lay the groundwork for improving clinical outcomes and sustaining long-term growth.***

141. On July 26, 2018, Jayson Bedford of *Raymond James* issued an analyst report on Abiomed titled "Abiomed - Beatable Estimates Should Drive Enthusiasm; Outperform (PT to \$425)." In the report, Bedford reported the following on the Company's Q1 2019 results:

**Recommendation:** We maintain our **Outperform** rating on ABMD as there was nothing thesis changing in F1Q results. While F1Q revenue (+36% y/y) may not have met some overly ambitious expectations, revenue still beat our estimate by 6%. High expectations combined with accelerated spending levels and an overall tough tape for growth assets, led to today's stock underperformance (-11% vs. flat for the S&P). We take comfort in the fact that, although we raised our estimates, we still believe these estimates are beatable and historically, ABMD has been a stock that gets bought back on earnings-related weakness.

\* \* \*

**Guidance still seems beatable:** We raised our F2Q/FY19 revenue estimates by 2%/1%. The revenue growth guidance assumes a deceleration to ~27% for the rest of the year, which we view as unlikely. The front-end loaded spending and physician training gives us more confidence in revenue upside as the year progresses, which gives way to margin improvement. We note that the TCT meeting takes place in late September this year and could be a possible headwind to Impella volumes in 2Q. However, given the numerous drivers (expanding sales force, larger training initiative, full launch of RP, and traction in Japan), we view FY19 guidance as conservative.

\* \* \*

**Valuation:** At ~15x our CY20 sales, ABMD is trading well above its high growth peers (~10x). However, Abiomed has a faster growth rate, better margin profile, monopolistic market structure, and an underpenetrated end market. This adds durability to the growth runway. As such, we believe a premium multiple is warranted.

142. On July 26, 2018, Raj Denhoy of *Jefferies* issued an analyst report on Abiomed titled “Abiomed (ABMD) - A Very Positive Q (Despite Stock Reaction); Still Best Growth Story in Medtech.” In the report, Denhoy reported the following on the Company’s Q1 2019 results:

### Key Takeaway

ABMD put up another solid Q: \$6mn/\$0.01 beat, +37% WW Impella growth, + \$32% US Impella, +75% OUS Impella. Despite the strong result, however, ABMD shares are down sharply. We’ve seen this before and note that nothing has fundamentally changed. ABMD remains the cleanest growth story in our space with expansive markets, beneficial clinical data, supportive reimbursement, and no competition. The 1Q performance reinforces this view, keeping us firmly at Buy.

Stock down good print? Sticking with the best growth story in medtech. Aside from top-line growth, US patient utilization was +30% (+27% last year), Germany revenue grew +42%, protected PCI +24% (+26% last Q), shock +37% (+43% last Q); PCI and shock performances are meaningful considering they show little fall off from the results seen in F4Q (seasonally strongest). The outlook remains exceedingly positive, with penetration in PCI/Shock hovering around 10%, physician training accelerating (750 physicians trained in Q), and new markets (Japan, India) just getting started. As such, today’s sell-off looks like yet another chance to own ABMD shares on an unwarranted sell off.

143. On August 2, 2018, Defendants filed Abiomed’s Quarterly Report on Form 10-Q with the SEC, reporting the Company’s financial and operating results for its first fiscal quarter 2019 ended June 30, 2018 (the “1Q 2019 10-Q”). Defendant Trapp signed the Form 10-Q, and Defendants Minogue and Trapp each certified this filing.

144. Defendants' statements concerning the sustainability of the Company's growth and expanded adoption and use of the Impella Platform contained in ¶¶137-40 were materially false and misleading for the reasons described in ¶136.

### **3. Second Fiscal Quarter 2019 Results – November 1, 2018**

145. On November 1, 2018, Abiomed issued a press release, attached to a Form 8-K signed by Defendant Trapp, announcing its financial and operating results for its second quarter of fiscal year 2019 ended September 30, 2018. The press release reported "second quarter fiscal 2019 revenue of \$181.8 million, an increase of 37% compared to revenue of \$132.8 million for the same period of fiscal 2018." Abiomed's revenue growth would then decline over the Company's following three fiscal quarters. Defendant Minogue was again quoted stating that the Company was successfully "*executing [its] plan for sustainable growth.*"

146. That same day, the Company hosted a conference call to discuss its quarterly results for Q2 2019. During this call, Defendant Minogue stated that, "*Abiomed is positioned for sustainable growth and building the field of heart recovery with disciplined execution*" and "*we are executing our plan for sustainable growth.*"

147. Regarding the adoption of the pumps in the Impella Portfolio, Defendant Minogue touted the expansion, stating in pertinent part:

*We are confident in our future with Impella growth opportunities of several hundred thousand patients, with new and existing indications, new products and new geographies.*

\* \* \*

We will be updating what we call the TAM in the near future, but what we have asked to do and have communicated to the investors is we recognize that with the expansion of the labels, both for high-risk PCI and cardiomyopathy and other forms of shock, we want to maintain the focus on the patients that currently have a critical need, that are in the hospital today or are being bounced around the hospitals. *And we believe we'll get 100% of that 231,000 patients.*

And then in the future, we'll update with some of these new numbers on the expansion with the labels and with the new products.

148. Defendant Trapp also stated:

*We will continue to make these growth investments as we are still in the early stages of market penetration in our top 3 targeted countries of the U.S., Germany and Japan.*

\* \* \*

*We are well positioned to deliver our plan for 2019 and beyond.*

\* \* \*

*So again, we'll continue to grow at a pace that we think is sustainable, and our goal is to remain one of the fastest-growing, most profitable medtech companies in the market.*

149. During the call, Defendant Minogue also represented that the Impella RP device was now being used at 368 sites. Furthermore, when questioned by analysts regarding the device's "rollout to date," Defendant Minogue stated that the Impella RP was enjoying substantial demand, and stressed Abiomed's commitment to training and protocols, stating in pertinent part:

*Margaret, there's a lot of interest in the RP because there's no other product like it.* The challenge is there's no other product like it. So it's the venous vein and interventional cardiologists are not used to necessarily placing devices in the right side compared to the left side so that's a bit of a training issue and then we have multiple patients in the RP.

You have patients that are failing or struggling after an implantable LVAD or they can't come off pump after transplant, all the way to patients that have RV infarcts or severe shock with biventricular failure. So again, it's about embedding the training and the timing and the protocols into what we're doing, but we feel that that product is critical to improving the outcomes, especially around shock.

150. On November 1, 2018, Margaret Kaczor of *William Blair* issued an analyst report on Abiomed titled “Abiomed - Another Strong Quarter Across the Board; Multiple Opportunities to Drive Growth.” In the report, Kaczor reported the following on the Company’s Q2 2019 results:

Abiomed reported another strong quarter of results, with fiscal second-quarter 2018 revenue of \$181.8 million (up 37% year-over-year), ahead of our and the Street estimate of \$175 million.

Encouragingly, the beat was driven by strength across the board, with continued momentum in Shock and HRPCI (both up 30%), and continued adoption in international markets, especially Germany and Japan. Despite ongoing investments in education and training, operating margins also came in 220 basis points above our estimate as they benefited from higher Impella volumes and better gross margins than we anticipated.

Management raised the low end of its fiscal 2019 revenue guidance, now \$765 million to \$770 million (+29% to +30% year-over-year) versus our and the Street’s prior estimates for \$764.4 million and \$770.5 million. Recall that reps have historically been brought on for annual training in the fiscal second quarter ending June, but because this year’s TCT meeting was held in September management has started hiring and training reps in October (fiscal third quarter). As a result, management expects a step-up in fiscal fourth-quarter growth as fully trained reps enter the field. Further, while second-half sales have historically been in the range of 54%-55% of full-year sales, guidance implies the second half of fiscal 2019 will make up 53% of full-year sales, which we believe is conservative.

We believe there is room for upside to guidance given the multiple catalysts that should push growth higher, including: expanded High-Risk PCI (HRPCI) and Shock indications (management mentioned already seeing some benefit here), ramping up RP and Japanese sales (new trained sites in Japan were already above our expectations), ongoing momentum from the independent National Cardiogenic Shock Initiative, and new product introductions (optical sensor in the U.S., Impella 5.5 in Europe).

\* \* \*

### **Conclusion and Stock Thoughts**

While the bar was high this quarter given the valuation, the fundamental performance was strong, and we believe management is appropriately investing in its business to drive growth, which should pay off as comps become more difficult in the second half of the fiscal year.

\* \* \*

**Operating Margin.** Despite ongoing investments in the company's commercial initiatives (training, education, manufacturing), Abiomed delivered a strong quarter of operating margins, beating our estimates by 220 basis points. Operating margins of 27.7% were up 380 basis points year-over-year largely due to higher Impella sales.

We continue to view management's 28%-30% margin guidance for the year as achievable, particularly as its first-half investments should positively impact the second half. Typically second-half operating margins come in stronger than the first half, and we'd assume the same this year, driven by higher second-half revenues over the first and leverage in the SG&A line as a percentage of total revenues. We model operating margin of 28.5% in fiscal 2019, representing 200 basis points of expansion for the fiscal year. That said, our estimate may well be conservative.

151. On November 1, 2018, Bruce Nudell of *SunTrust Robinson Humphrey* issued an analyst report on Abiomed titled "Strong 2Q Results; Raised FY 2019 Lower End Sales Guidance Range." In the report, Nudell reported the following on the Company's Q2 2019 results:

**2Q19 US Impella Revenues Increased 34%:** Abiomed reported FY 2Q19 US Impella revenues of \$152.2M (34% reported), above our estimate of \$147.0M (29.4% reported) and above consensus of \$144.6M (27.3% reported), while US Impella patient usage increased 29%. Ex-US Impella revenues increased to \$23.1M (67.4% reported), above our estimate of \$20.7M (50.0% CC, 49.9% reported) and below consensus of \$24.0M (73.7% reported). Total sales of \$181.8M (36.9% reported) were above our estimate of \$173.8M (30.9% CC & reported) and above consensus of \$175.4M (32.1% reported). GM of 83.6% was slightly below our estimate by ~40bps and below consensus by ~20bps, and OM of 27.7% was above our estimate by ~90bps and above consensus by

~120bps. The company reported EPS of \$1.09, however, excluding \$0.28 of stock comp tax benefits, results in \$0.81 comparable EPS, which was above our estimate of \$0.74 and above consensus of \$0.73.

\* \* \*

**FY 2019 Model Estimates:** The company increased its sales guidance range to \$765M-\$770M (29%-30% reported) from a prior \$755M-\$770M (27%-30% reported), which is slightly below our estimate of \$773.9M (30.1% CC, 30.3% reported) and in-line with consensus of \$770.5M (29.8% reported). Our investment hypothesis for ABMD is predicated by what we perceive to be a very long tailed opportunity. Additionally, the company is reaffirming its GAAP operating margin guidance range of 28%-30%.

152. On November 6, 2018, Defendants filed Abiomed's Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarterly period ended September 30, 2018 (the "2Q 2019 10-Q"). Defendant Trapp signed the Form 10-Q, and Defendants Minogue and Trapp each certified this filing. For the quarter, Defendants reported a net income of \$50.13 million, or \$1.09 per diluted share, on revenue of \$181.78 million, compared to a net income of \$24.50 million, or \$0.54 per diluted share, on revenue of \$132.82 million for the same quarter the year prior.

153. Defendants' statements concerning the sustainability of the Company's growth and expanded adoption and use of the Impella Platform contained in ¶¶145-49 were materially false and misleading for the reasons described in ¶136.

#### **4. Pre-Announcement of Third Fiscal Quarter 2019 Results – January 7, 2019**

154. On January 7, 2019, Defendants issued a press release, attached to a Form 8-K signed by Defendant Trapp and filed before the market opened, pre-announcing Abiomed's financial and operating results for the third quarter of fiscal 2019 ended December 31, 2018. That press release announced "third quarter fiscal 2019 revenue of approximately \$200.6 million,

an increase of 30% compared to revenue of \$154.0 million for the same period of fiscal 2018.”

The press release also touted year-on-year growth in Impella product revenue of 27%, and year-on-year growth in U.S. Impella patient usage of 24%.

### **5. Third Fiscal Quarter 2019 Results – January 31, 2019**

155. On January 31, 2019, Defendants issued a press release, attached to a Form 8-K signed by Defendant Trapp and filed pre-market open, reporting Abiomed’s financial and operating results for the third quarter of fiscal 2019 ended December 31, 2018. Despite revenue growth dropping to 30% year-on-year growth for the quarter, as compared to the 37% reported in Q2 2019, the release touted “[r]ecord [r]evenue.” The press release also quoted Defendant Minogue, who again championed Abiomed’s sustainable growth. Specifically, Defendant Minogue was quoted as stating, in relevant part:

We are proud of our 100,000th patient milestone and we will continue to grow the field of heart recovery and improve patient outcomes by partnering with our customers to use real-world data to identify and validate best practices and protocols. . . . ***We remain focused on disciplined execution and sustainable growth so that even more patients around the world can benefit from heart recovery.***

156. That same day, the Company hosted a conference call to discuss its quarterly results for Q3 2019. During this call, Defendant Minogue represented that:

Abiomed is investing to improve clinical outcomes around both survival and native heart recovery with on-site and on-call support 24/7 and tracking outcomes on nearly all commercial patients. No other company in this space provides this level of support to help improve patient outcomes.

\* \* \*

***Additionally, we are investing in the commercial distribution to prepare for the expansion of products in the short and midterm, such as Impella CP, Impella Connect, Impella 5.5 and Impella RP.***

157. Also on the call, Defendant Trapp stated:

Keep in mind that the 30% was our 5-year operating margin target that we communicated 3.5 years ago. ***So we're ahead of that projection, and we will continue to drive for best-in-class performance.***

\* \* \*

What makes Abiomed really unique is that we've been able to deliver consistent top-tier financial results, while at the same time making significant strategic investments in the business.

\* \* \*

***And so we're going to continue to grow at a pace that we think is sustainable with a focus on patient outcomes.*** And again, as Mike mentioned, our goal remains to be one of the fastest-growing, most profitable med-tech companies in the market. And so I think it's more comps than anything else.

158. On January 31, 2019, Chris Pasquale of *Guggenheim Securities* issued an analyst report on Abiomed titled “ABMD - Pipeline Progress Increases Our Conviction On Growth Runway; Reiterate BUY.” In the report, Pasquale reiterated his “conviction in the sustainability of Abiomed's growth trajectory and the durability of its competitive moat,” stating in pertinent part:

**Key Message:** ABMD's full F3Q19 results were as preannounced on the top line, while EBITA margin topped consensus by an impressive 80bps. With headline numbers already disclosed, we thought the most interesting data points from the call were on the pipeline, which we believe remains underappreciated by investors. Management provided positive updates on new products (Connect, 5.5, ECP), indications (STEMI), and geographies (Japan), **all of which increases our conviction in the sustainability of Abiomed's growth trajectory and the durability of its competitive moat.** We reiterate our BUY rating.

\* \* \*

**Turning back to the quarter, Impella turned in another strong performance across all three of its major geographies.**  
Domestic Impella sales rose 27% to \$165.7M, \$2.1M above consensus prior to the company's early January pre-announcement.

\* \* \*

**Good line of sight to \$1B in revenue and beyond; reiterate BUY.** For FY19, our model now calls for EPS of \$3.64 (+52.2%) on total revenues of \$781.6M (+31.6%). This compares to our prior forecast of \$3.65 and \$776.3M, respectively. Longer-term, we continue to believe that Abiomed has a long growth runway ahead of it as it penetrates existing market opportunities that we estimate at \$6-7B. . . . We forecast worldwide Impella sales rising to \$1.8B by FY23, a 24% CAGR. Our model calls for operating margins to expand from 29% to 37% over that same period. Few (if any) companies in the sector can realistically aspire to this kind of outlook.

159. On January 31, 2019, David R. Lewis of *Morgan Stanley* issued an analyst report on Abiomed titled “Abiomed - Ex US to Drive Durable and Above Peer Growth.” In the report, Lewis reported the following on the Company’s Q3 2019 results:

**3Q pre-announced beat.** Abiomed pre-announced 3FQ sales of \$201mn, beating consensus estimates of \$195mn and MSe of \$191mn, representing ~30% y/y growth which was an important optical expectation into the quarter []. US Impella sales decelerated by ~4 pts, comp-adjusted as PCI momentum was lower while Shock was stable. That said, we note the sequential momentum for the 6 months period was +4 pts for PCI and relatively stable for total patient growth. Ex US growth continued to surprise to the upside as Europe accelerated by ~10 pts and Japan continues to roll out ahead of schedule, which will be a key theme into FY20 [].

**Into the end of the year...** Management raised FY19 sales guidance by ~\$10mn to ~\$780mn, ~\$5mn more than the quarterly beat. **Guidance implies ~25% y/y growth which optically is ~6 pt lower q/q for y/y growth.** Adjusting for the tougher comp, guidance implies 2 pts of momentum deceleration, which could prove conservative, as we've seen [n] 2-4% beats all year. **We note a \$3mn (1-2%) beat implies momentum stability.** We model ~1 pt of acceleration in the US into 4Q, which is a reversal from the

~4 pts of deceleration into 3Q. In Europe we model momentum stability which may prove conservative given the 3FQ recovery in Europe and outlook for broader coverage in UK and smaller European markets

160. On February 5, 2019, Defendants filed Abiomed's Quarterly Report on Form 10-Q with the SEC, reporting the Company's financial and operating results for the quarterly period ended December 31, 2018 (the "3Q 2019 10-Q"). Defendants Minogue and Trapp certified this filing. For the quarter, Defendants reported a net income of \$44.86 million, or \$0.97 per diluted share, on revenue of \$200.56 million, compared to a net income of \$13.45 million, or \$0.29 per diluted share, on revenue of \$154.02 million for the same quarter the year prior.

161. Defendants' statements concerning the sustainability of the Company's growth and expanded adoption and use of the Impella Platform contained in ¶¶155-57 were materially false and misleading for the reasons described in ¶136.

**C. Materialization of the Risks and Continued Materially False and Misleading Statements and Omissions**

162. Text that is **bolded and underlined** indicates the materialization of previously undisclosed risks. Text highlighted in ***bold and italics*** continues to indicate statements alleged to be materially false and misleading.

**1. Fourth Fiscal Quarter and Full Year 2019 Results – May 2, 2019  
(First Partial Disclosure)**

163. On May 2, 2019, Abiomed issued a press release, attached to a Form 8-K signed by Defendant Trapp, reporting Abiomed's financial and operating results for the fourth quarter and full year 2019 ended March 31, 2019. With regard to Abiomed's revenue for those periods, the press release stated, in relevant part:

Abiomed, Inc., a leading provider of breakthrough heart recovery and support technologies, today reported fourth quarter fiscal 2019 revenue of \$207.1 million, an increase of 19% compared to revenue of \$174.4 million for the same period of fiscal 2018. For

fiscal year 2019, total revenue was \$769.4 million, up 30% compared to revenue of \$593.7 million, and operating income was \$224.8 million, up 43% compared to operating income of \$157.1 million in fiscal year 2018.

164. For Q4 2019, the Company reported revenues of only \$207 million, more than \$10 million short of analysts' expectations, and up only 19% as compared to Q3 2019 revenue, and less than half of the Q4 2018 growth rate of 40%. The press release quoted Defendant Minogue, who acknowledged Abiomed's disappointing Q4 2019 results, but nonetheless touted the Company's long-term outlook and plan of action to "*correct the course.*" Specifically, Defendant Minogue was quoted in the press release as stating, in relevant part:

**Q4 did not meet our expectations. I take full responsibility for our disappointing performance given a soft March, and we have already initiated a plan of action to correct the course.**

However, Abiomed had a solid year with 30% growth and improvement in margins. Most importantly, Abiomed's clinical support, training, and education helped improve patient outcomes in both high-risk PCI and cardiogenic shock. Multiple publications continue to validate the benefits of Impella supported PCI and Impella best practices to help improve survival in cardiogenic shock. ***I am confident in our innovation and business today as well as long-term outlook for Abiomed.*** We are creating the new Field of Heart Recovery.

165. With regard to Abiomed's full year 2020 outlook, the press release stated, in relevant part:

#### FISCAL YEAR 2020 OUTLOOK

***The company is giving its fiscal year 2020 guidance for total revenues to be in the range of \$900 million to \$945 million, an increase of 17% to 23% over the prior year.*** The company is also giving its fiscal year 2020 guidance for GAAP operating margin to be in the range of 29% to 31%. The company plans to give another formal forecast for the fiscal year on the next earnings call.

166. That same day, the Company hosted a conference call to discuss its quarterly results for Q4 2019. During this call, Defendant Minogue reiterated the Company's "***plan of action to correct the course,***" stating in relevant part:

Thank you, Ingrid, and good morning, everyone. **By now you've seen our press release, and I want to begin by recognizing that our performance in Q4 did not meet our expectations. I take full responsibility for our disappointing performance given a soft March. And I will discuss momentarily the changes and plan of action we have already initiated to correct the course.**

**In the quarter, we generated \$207 million in revenue, up 19%.** We had anticipated a tough comparison given the 40% growth in the prior year period, **but our results were short of our goal of 25% growth or \$218 million.** Operating margins for Q4 were strong and expanded to 31.6%.

For the full fiscal year, revenue of \$769 million increased 30% versus the fiscal year 2018. Additionally, operating margins increased to 29.2%. ***In fiscal '19, we remain one of the fastest-growing GAAP profitable medical device companies. Abiomed has a long and proven track record of execution, posting over 20% in organic revenue growth for 18 consecutive quarters or 4.5 years while significantly expanding full year operating margins from 12.5% to 29.2%.*** During this time, we also invested nearly \$1 billion in innovation, clinical research and distribution. ***We remain confident in our business and our short to long-term outlook. We're confirming that our investment thesis remains fully intact.***

For today's call, I will cover 3 topics: first, **I will discuss the Q4 lessons learned and the actions already taken for Q1. . .**

\* \* \*

**So first, on Q4. It is important to note that our business typically sees significant sequential performance in Q4. Unfortunately, this is – did not occur because of the slower growth in March in patient utilization. We believe this occurred as a result of customer confusion stemming from the February 4 FDA letter to health care providers from the FDA, coupled with our response to prioritize Impella RP and shock which unintentionally distracted our focus away from Protected PCI execution. Unfortunately, this FDA letter to health care providers was misinterpreted by some media**

outlets and health care providers who inaccurately reported that Impella RP, or Impella, was being recalled or had overall safety issues that were being reviewed by the FDA. This was clearly not the case, which we clarified in our ACC press release, March 18.

We believe this noise negatively impacted our elective high-risk PCI patients in the cath Lab specifically in March. We also believe competitive companies likely capitalized on the confusion with our customers. Additionally, contracted survey companies called our customers to inform them of the FDA letter and questioned if they would reduce using Impella until final resolution. However, our internal shift in focus did likely yield improved clinical outcomes for Impella RP patients and resulted in a record quarterly revenue for Impella RP. There are other miscellaneous items that may have had an impact in the quarter, but generally, they fall into 2 categories: external noise or internal focus.

*We have already made the following changes to address the March performance.* The Impella RP post-approval study was presented and press released at the ACC meeting on March 18. The FDA now differentiates patients in the Recover Right protocol from salvage patients with right ventricular failure in shock for 48 hours or more. To be clear, the patients in the postapproval study that met the FDA criteria for right heart failure had similar outcomes to the FDA RP Recover Right Study, which led to the exclusive FDA approval. With the postapproval study submitted to the FDA, we anticipate a final closing FDA letter to health care physicians to be issued to our customers by the end of our fiscal year Q1 that stresses the importance of early identification of right ventricular cardiogenic shock and reinforces our safe and effective approval for Impella RP. Additionally, we have taken the following steps, which we believe will eliminate noise and highlight the clinical benefits of Impella for both interventional cardiologist and the heart failure community, which includes heart surgeons. We capitalized on the timing of our annual Abiomed Field Meeting with 3 days of training, with over 400 employees and on all the new publications for high-risk PCI and shock. This meeting was last week.

We also highlighted our last two press release – press releases on both high-risk PCI and cardiogenic shock. We have created 2 new U.S. regions for our core business, increasing the number of territories and account managers allowing us to go deeper with interventional cardiologists. We added 4 new MDs to our medical office to expand our training and education

programs in headquarters at our Heart Recovery Institute and regionally in the field, and we also expanded our distribution channel focused on the heart team, including heart surgeons, to maintain our momentum on Impella 5.0 and Impella RP and prepare for future Impella 5.5 launch. We believe these actions we have taken will help reduce the noise. *However, it will likely require at least a quarter of execution to eliminate all confusion on the Impella platform.*

*For this reason, we are disclosing today that our U.S. April growth rate showed improvement over March, but it is not yet where we want it to be. We will rise up.* We have more work to do to educate our customers on improving outcomes and recent publications. *And we will leverage the final pending FDA confirmation letter.* Our business is based on the integrity of our products, the relationships we have with hospitals and physicians and our reputation. When there is confusion in the market about the safety of our products, it takes time and effort to get back on track.

167. On May 2 2019, Margaret Kaczor of *William Blair* published an analyst report on Abiomed titled “Abiomed – “FDA Letter Confusion Causes a Rare Miss in Fourth Quarter; Execution Should Win Out as Fundamentals Remain Strong.” Kaczor’s report noted, in part:

Weakness in the quarter was largely due to slower-than-anticipated Impella growth in the month of March, following the FDA’s Dear Doctor letter on Impella RP. Management believes the letter created confusion among surgeons regarding the safety and efficacy of Impella in other indications, namely elective high-risk PCI (HRPCI).

Following the publication of the letter, Abiomed refocused much of its training and education efforts in the fiscal fourth quarter on Impella RP. While the company successfully reaccelerated RP growth in the quarter (+16%, compared to +1% last quarter), it came at the expense of HRPCI , which we estimate decelerated to 12% growth in the quarter domestically (down from over 25% in the first through third quarters of 2019). While cardiogenic shock growth also came in below expectations (+17% compared to +25% last quarter), it was less impacted from the company’s focus on RP given the higher utilization of RP in shock.

**Guidance:** Given the slower-than-expected end to fiscal 2019, management provided fiscal 2020 guidance below the Street and management’s own initial expectations. Specifically, full year

sales guidance came in at \$900 million to \$945 million (up +17% to 23%), well below our and the Street's estimate for \$970.6 million and \$988.6 million heading into the print.

Management noted fiscal fourth-quarter growth was approximately 6% lower than guidance, and the company similarly decreased its fiscal 2020 guide by 6% (at the midpoint) . This implies management anticipated guiding to a range of 24% to 28% fiscal 2020 growth—more in line with the mid-to-high 20% growth reported over the past several years. **That said, management noted U.S. volumes in April have already started to reaccelerate from the March lows, though they are not where they should be to deliver consistent 25% + growth. As a result, management has started taking action on plans they believe will help Abiomed deliver sustainable growth, with improvements expected to be seen through fiscal 2020.**

168. On May 2, 2019, *Jefferies* published an analyst report titled “4Q Miss Worse Than Expected But With Issues Seeming Fixable, It’s Time to Own” that stated the results for the quarter were “worse than feared.” That report also noted that Defendants blamed the disappointing revenue results “squarely on the FDA warning letter in early February,” in that it “caused both internal focus issues and external noise that conspired to cause a big fall off in sales.”

169. On May 3, 2019, Chris Pasquale of *Guggenheim Securities* published an analyst report titled “ABMD – Thoughts Post a Disappointing F4Q,” which stated that the Company’s “deceleration across multiple markets that points to RP as being the culprit.” Similar to the analyst report discussed in the previous paragraph, *Guggenheim Securities* attributed the disappointing revenue to both internal and external factors for Abiomed. Pasquale noted the following in his report:

**RP confusion short circuits an otherwise strong year.** One of the questions we got repeatedly yesterday was whether we believed that the fallout from the FDA’s physician communication regarding the Impella RP post approval study was really the culprit for the 4Q shortfall. That skepticism on the part of investors was likely driven in part by the fact that so many had done their own

checks during the quarter and heard from physicians that their left-sided Impella utilization was unlikely to be affected. While our own checks also suggested that most physicians took the letter in stride, our sense is that the distraction from the noise surrounding RP, the ambiguity in the FDA's language, and the bandwidth that the issue consumed for Abiomed's sales force all combined to drive weaker procedure volumes in March. And while bears might argue that the deceleration in protected PCI cases (+11% in 4Q vs. +27% in 1H19) is indicative of market saturation or pushback on utilization of Impella is that setting, that hypothesis doesn't explain why both Europe and Japan slowed at the same time. It's this concurrent deceleration across multiple markets that points to RP as being the culprit, in our view, as the FDA's megaphone reaches far beyond the U.S.

**Where do we go from here? Management indicated on Thursday's call that procedure volumes accelerated in April. While they remained depressed relative to the company's Jan/Feb run rate, this is an encouraging sign that Abiomed's efforts to assuage what concerns were out there are having a positive impact.** Next up should be a final communication from the agency in which it lays out the full findings from its investigation.

170. On May 23, 2019, Defendants filed Abiomed's Annual Report on Form 10-K with the SEC, reporting the Company's financial and operating results for the fiscal year ended March 31, 2019 (the "2019 10-K"). Defendants Minogue and Trapp certified this filing. For the fiscal year 2019, Defendants reported a net income of \$259.02 million, or \$5.61 per diluted share, on revenue of \$769.43 million, compared to a net income of \$112.17 million, or \$2.45 per diluted share, on revenue of \$593.75 million for fiscal year 2018.

171. Defendants' statements concerning the significant decrease in Abiomed's revenue growth and Impella adoption contained in ¶¶164-66 were materially false and misleading for the reasons described in ¶136.

## **2. First Fiscal Quarter 2020 Results – August 1, 2019 (*Final Disclosure*)**

172. On August 1, 2019, before the market opened, Defendants issued a press release announcing Abiomed's financial and operating results for the first quarter of fiscal year 2020

ended June 30, 2019. Among other results, the Company disclosed Abiomed’s third consecutive quarter of slowing revenue growth, reporting “first quarter fiscal 2020 revenue of \$207.7 million, an increase of 15.4% compared to revenue of \$180.0 million for the same period of fiscal 2019.” This represented a significant decrease in revenue growth from 1Q 2019. Commenting on the Company’s disappointing financial results, Defendant Minogue revealed that the Company’s “new training programs, organizational changes in distribution, and [] external initiatives. . . will require time to drive more growth in the future.”

173. The Company also slashed its previously issued full-year 2020 guidance from total revenues in the range of \$900-945 million to total revenues in the range of \$885-925 million, which fell roughly \$22 million short of market expectations. Abiomed informed investors that in an effort to right the ship and kick-start growth, the Company adjusted both its overall strategy in the United States, as well as the Company’s distribution model. The Company also conceded that training physicians on “Impella access, closure and ICU management” was Abiomed’s “biggest obstacle” among doctors not currently utilizing Impella pumps. On this news, Abiomed’s stock price fell \$73.69 per share, or 26.45%, to close at \$204.87 per share on August 1, 2019.

174. On August 1, 2019, pre-market, Defendants issued a press release announcing Abiomed’s financial and operating results for the first quarter of fiscal year 2020 ended June 30, 2019. Among other results, the press release disclosed Abiomed’s third consecutive quarter of slowing revenue growth, reporting first quarter fiscal 2020 revenue of \$207.7 million, a decrease in revenue growth of over 58% compared to the 37% increase in revenue reported in 2Q 2019—*i.e.*, first quarter 2020’s revenue growth of 15.4% (compared to first quarter 2019) represented a decrease of over 58% from second quarter 2019’s revenue growth of 37% (compared to second

quarter 2018), and a decrease of nearly 50% from third quarter 2019’s revenue growth of 30% (compared to third quarter 2018).

175. The Company also slashed its previously issued full-year 2020 guidance from total revenues in the range of \$900-945 million to total revenues in the range of \$885-925 million, which fell roughly \$22 million short of market expectations. Specifically, the press release stated, in relevant part:

Abiomed, Inc a leading provider of breakthrough heart recovery and support technologies, today reported first quarter fiscal 2020 revenue of \$207.7 million, an increase of 15.4% compared to revenue of \$180.0 million for the same period of fiscal 2019. Operating income was \$60.7 million, up 30%, compared to \$46.7 million in the same period of fiscal 2019.

**“In Q1, we implemented new training programs, organizational changes in distribution, and launched external initiatives that will require time to drive more growth in the future,”** said Abiomed Chairman, President and CEO, Michael R. Minogue. “We are confident in our ultimate global adoption because we know that our innovation improves clinical outcomes and patient quality of life.”

\* \* \*

#### FISCAL YEAR 2020 OUTLOOK

**The company is revising its fiscal year 2020 guidance for total revenues to be in the range of \$885 million to \$925 million, an increase of 15% to 20% over the prior year. The company is also revising its fiscal year 2020 guidance for GAAP operating margin to be in the range of 28% to 30%.**

176. On this news, Abiomed’s stock price fell \$73.69 per share, or 26.45%, to close at \$204.87 per share on August 1, 2019.

177. Following the Company’s disclosure of its 1Q 2020 financial performance and revised guidance, *Investor’s Business Daily* published an article raising concern with Defendant Minogue’s prior public statements, titled: “This Medtech’s CEO Promised To ‘Correct The

Course’ – That Didn’t Happen.” That article stated that “Abiomed stock collapsed Thursday after the medical technology company lagged Wall Street’s full-year guidance expectations by more than \$22 million.” The article also described Abiomed as “stuck in a trend of deceleration.”

178. Similarly, *Bloomberg* published an article on August 1, 2019 detailing investor concerns about the slowdown in revenue titled: “Heart-Pump Stock Goes From First to Worst as Growth Cools.” *Bloomberg* noted that Abiomed was a “former darling among stock investors” but the disappointing revenue and guidance “wiped out a year and a half of gains.” *Bloomberg* described Abiomed as “the worst performer in both the sector and the broader benchmark this year.”

179. Also on August 1, 2019, *Stephens* published an analyst report titled “First Look: Not as Scripted, ABMD Missed Fiscal 1Q & Lowers FY20 Guidance,” which noted that “a guidance increase [for FY20] was expected in conjunction with the 1Q,” but that “was not the case.” On that same day, *Morgan Stanley* issued an analyst report titled “Now Looking More Structural; Downgrading to EW,” which stated that “slower growth trends are more structural and we are less confident in an acute recovery.” That report also noted that Abiomed lacked any “near-term catalyst” to restart the revenue growth.

180. On August 1, 2019, *Guggenheim Securities* published an analyst report titled “ABMD – Disappointing F1Q as Expected Recovery Fails to Materialize,” which attributed the Company’s failure to rebound to disappointing Impella sales in the U.S. On August 2, 2019, *Guggenheim Securities* followed up with another analyst report titled “ABMD – Lack of Recovery Suggests Deeper Issues; Downgrading to NEUTRAL,” which noted that it was “increasingly likely that Abiomed is wrestling with structural challenges rather than a transient

headwind.” That report also estimated that there were still twice as many IABPs implanted than Impella pumps, contrary to Defendants’ assertions throughout the Class Period.

181. On August 2, 2019, *The Motley Fool* published an article titled “Abiomed is Still in the Growth Recovery Ward,” which stated that traders were “clearly not happy with the weak quarterly results and guidance cut.”

182. As a result of Defendants’ wrongful acts and omissions, and the precipitous decline in the market value of the Company’s securities, Plaintiff and other Class members have suffered significant losses and damages.

## **VI. ADDITIONAL SCIENTER ALLEGATIONS**

183. As alleged herein, Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements issued or disseminated in the name of the Company, or in their own name, were materially false and misleading; knew or recklessly disregarded that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt or access to information reflecting the true facts regarding Abiomed, their control over, or receipt, or modification of Abiomed’s allegedly materially misleading misstatements, were active and culpable participants in the fraudulent scheme alleged herein.

184. Defendants knew or recklessly disregarded the false and misleading nature of the information that they caused to be disseminated to the investing public. The ongoing fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity, or at least, the reckless disregard, of Abiomed personnel at the highest levels of the Company.

185. The following allegations all support a strong inference of scienter:

- (a) Statements by former Abiomed employees corroborate that Defendants knew or were reckless in not knowing that the Company's growth rate was slowing as early as the start of the Class Period;
- (b) Stock sales by Abiomed insiders including Defendant Minogue, COO Weber, and Director Sutter during the Class Period were highly unusual and suspicious in timing; and
- (c) The Impella devices comprised all of Abiomed's revenues and thus Defendants, knew or should have known of the slowdown in growth and market saturation.

**A. Statements By Former Abiomed Employees Corroborate That Defendants Knew Or Were Reckless In Not Knowing That the Company's Growth Rate was Stalling by the Start of the Class Period**

186. The CWs make clear that Defendants' false and misleading statements were not simply a mistake or mismanagement—but rather that the Defendants knew or recklessly disregarded that the Company's growth rate was stalling by the start of the Class Period.

187. As detailed and corroborated by multiple former employees of Abiomed (¶¶68-123), Defendants knew or recklessly disregarded that:

- (a) Year-on-year revenue growth of 30% was unsustainable, primarily because the Company had already saturated the market for Impella pumps, and reorder performance was weak.
- (b) Abiomed's sales practices throughout the Class Period—which were particularly aggressive at the end of the quarter—could not support the growth the Company promised the market, and Abiomed sales representatives risked damaging long-term relationships with hospitals.

(c) Abiomed management's laser focus on the Company's share price during the Class Period led to extremely aggressive sales goals and questionable sales tactics.

(d) Doctors were reluctant to use Impella pumps, questioned their effectiveness, had issues with implantation, even looking for excuses not to use Impella pumps in some instances, and were unwilling to use the pumps beyond their very specific FDA indications.

(e) Abiomed's revenue growth was hindered by a disconnect between the Company's two types of field representatives - its Clinical Consultants and its Cardiology Account Managers - who had competing interests. Clinical Consultants were nurses or care practitioners with experience in the cardiac space (but with little, or no, sales experience), while CAMs were Abiomed employees with medical device sales experience.

(f) Broader access to the Company's Impella clinical data would lead to additional questions about the integrity of the Company's data, and

(g) Tracking data from Salesforce related to Impella sales, implantation, and surgical outcomes showed that Impella use and, thus, reorder performance during the Class Period was weak.

**B. Insider Stock Sales During the Class Period Were Highly Unusual and Suspicious**

188. Abiomed insiders including Defendant Minogue, COO David Weber, and Director Martin Sutter engaged in stock sales during the Class Period that were suspiciously timed and dramatically out of line with their prior trading practices. As a result of these Class Period trades, these insiders profited from the artificial inflation embedded in the trading price of Abiomed stock caused by Defendants' false and misleading statements and omissions to investors during the Class Period. These sales occurred before Defendants disclosed that

Abiomed's growth rate was stalling and while Abiomed stock was trading near Class Period highs, and before substantial declines in the price of the stock.

**1. The Value and Amount of Trading by the Individual Defendants Was Highly Unusual**

189. The Class Period sales of Abiomed stock by Defendant Minogue, COO David Weber, and Director Martin Sutter were highly unusual and suspicious as measured by (i) the total amount of shares sold, (ii) the percentage of shares sold compared to the number of total shares available for sale during the Class Period, (iii) the contrast with the these individual's own prior trading history, and (iii) the timing of the sales. Such sales therefore raise a strong inference of scienter.

190. To evaluate the insider selling activity, Lead Plaintiff used the publicly available trading data that certain officers and directors are required to report to the SEC on Form 4. Lead Plaintiff analyzed the trading by the Individual Defendants during the Class Period and during the equal-length period immediately preceding the Class Period beginning February 2, 2017 to May 2, 2018 (the "Control Period"). The Forms 4 filed during the Class Period and Control Period are hereby incorporated by reference, and a summary of the relevant transactions are set forth in Appendix A, annexed hereto.

191. To analyze the insider sales, Lead Plaintiff calculated the total sales by each of the officers and directors, together with the proceeds from such sales, during the Control and Class Periods. Those totals were then compared to identify whether the insider sales during the Class Period were consistent with their sales during the Control Period. The specific trading dates also were evaluated compared to the dates the truth was revealed. All of these analyses reveal that sales of Abiomed stock by Defendant Minogue, COO David Weber, and Director Martin Sutter during the Class Period were extremely large, highly unusual, and suspicious.

**CLASS PERIOD AND CONTROL PERIOD TRADING BY**  
**ABIOMED INSIDERS**  
**CLASS PERIOD TRADING**  
5/3/18 – 7/31/19

Officer/Director	Title	Number of Shares Sold	Proceeds
Minogue (Michael R)	CEO	105,000	\$46,166,898.68
Weber (David M)	COO	89,782	\$35,896,662.31
Sutter (Martin P)	Director	76,554	\$26,437,568.00
<b><i>Total Shares Sold During Class Period and Proceeds</i></b>		<b>271,336</b>	<b>\$108,501,128.99</b>

**CONTROL PERIOD TRADING**

2/2/17 – 5/2/18

Officer/Director	Title	Number of Shares Sold	Proceeds
Minogue (Michael R)	CEO	None	None
Weber (David M)	COO	59,000	\$7,518,885.38
Sutter (Martin P)	Director	None	None
<b><i>Total Shares Sold During Control Period and Proceeds</i></b>		<b>59,000</b>	<b>\$7,518,885.38</b>

**2. The Nominal Amount and Percentage of Abiomed Holdings Sold Were Extremely Large**

192. The proceeds from shares sold during the Class Period by Defendant Minogue, COO David Weber, and Director Martin Sutter were extremely large.

193. Defendant Minogue sold 105,000 shares of Abiomed stock during the Class Period for proceeds of more than \$46 million. In addition, during the Class Period, 80,329 shares of Defendant Minogue's Abiomed stock worth \$32.9 million was withheld by the Company to pay for his personal taxes in connection with Company-issued stock. ***Through these transactions, Defendant Minogue disposed of approximately 24.5% of his total shares***

*that were available for sale during the Class Period. During the Control Period, Defendant Minogue disposed of approximately 8.6% of his total shares that were available for sale.*

194. COO Weber sold 89,782 shares of Abiomed stock during the Class Period for proceeds of close to \$36 million. In addition, during the Class Period, 54,087 shares of Weber's Abiomed stock worth \$18.3 million was withheld by the Company to pay for his personal taxes in connection with Company-issued stock. *Through these transactions, Weber disposed of approximately 50.1% of his total shares that were available for sale during the Class Period. During the Control Period, Weber disposed of only 40.1% of his total shares that were available for sale.*

195. Director Martin Sutter sold 76,554 shares of Abiomed stock during the Class Period for proceeds of more than \$26 million. During the Control Period, Martin did not dispose of any of his Abiomed stock.

### **3. These Class Period Stock Sales Were Inconsistent With Prior Trading Practices**

196. The Class Period stock sales of Defendant Minogue, COO David Weber, and Director Martin Sutter were not only large in terms of proceeds, but also were inconsistent with these individuals' prior selling activity during the Control Period.

197. Indeed, during the Control Period (February 2, 2017 to May 2, 2018), Defendant Minogue and Director Martin Sutter sold absolutely none of their Abiomed stock.

198. During the Class Period, COO Weber received proceeds from his Abiomed stock sales of almost five times the proceeds he made from Abiomed sales during the Control Period. During the Control Period, Weber sold only 59,000 shares of his Abiomed stock for proceeds of approximately \$7.5 million compared to proceeds of almost \$36 million from his Class Period sales.

#### **4. The Timing of the Stock Sales Was Suspicious**

199. The Class Period stock sales of Defendant Minogue, COO David Weber, and Director Martin Sutter were suspiciously timed in large measure because they sold a vast number of shares after they learned of materially adverse information—but before the public disclosure of that same adverse information.

200. Most notably, Defendant Minogue sold all 105,000 shares of his Abiomed stock on June 21, 2018, after learning of, or recklessly disregarding the deceleration of the Company's revenue growth rate.

201. COO Weber sold the majority of his Class Period stock sales between June 18, 2018 and July 30, 2018 after learning, or recklessly disregarding the deceleration of the Company's revenue growth rate.

202. These sales by Defendant Minogue, COO David Weber, and Director Martin Sutter are also suspicious because they were made while they knew, or were deliberately reckless in not knowing, that the Company's growth rate was on a downward spiral.

#### **5. The Presence of 10b5-1 Trading Plans Adopted by the Individual Defendants Does Not Absolve Defendants of Liability**

203. Rule 10b5-1, 17 C.F.R. § 240.10b5-1, provides that a person will be deemed to have traded “on the basis of” material non-public information if the person engaging in the transaction was “aware of” that information at the time of the trade. To provide a safe harbor under the “aware of” standard, the SEC created an affirmative defense to insider trading claims for trades made pursuant to a binding agreement or plan (“10b5-1 Plans” or “Plans”). *See Selective Disclosure and Insider Trading*, 65 Fed. Reg. 51,716, at 51,727-28 (Aug. 24, 2000). Pursuant to SEC Rule 10b5-1(c), a 10b5-1 Plan is a defense to insider trading liability **only** if it is entered into by an insider “[b]efore becoming aware” of inside information, and was

established “in good faith and not as part of a plan or scheme to evade the prohibitions” against insider trading.

204. Because of this, insiders are advised to “design a trading plan with the intention that it will not be modified or amended frequently, since changes to the plan will raise issues as to a person’s good faith.” Thomson West, *Corporate Counsel’s Guide to Insider Trading and Reporting* § 12:26 (2006). Conversely, the adoption and/or modification of these plans while in possession of material non-public information is highly suspicious and supports a strong inference of scienter.

205. Although some of the Class Period stock sales by Defendant Minogue, COO David Weber, and Director Martin Sutter may have been made pursuant to 10b5-1 Plans, the circumstances of those sales are sufficiently suspicious to overwhelm any exculpatory inference that might otherwise have been available to pre-planned sales based on such Plans. Indeed, even if these officers and directors had entered into 10b5-1 Plans prior to the Class Period and traded within them consistently throughout the Class Period, such Plans are under heavy SEC scrutiny in light of a *Wall Street Journal* investigation that found that insiders who were trading pursuant to 10b5-1 Plans were still trading at opportune times and reaping better-than-expected results. According to the November 27, 2012 *Wall Street Journal* article, written by Susan Pulliam & Rob Barry, entitled “*Executives’ Good Luck in Trading Own Stock,*” executives trading pursuant to 10b5-1 Plans are still able to time their trades to avoid losses and increase earnings because trading plans are not public and can be canceled or amended at any time without disclosure.

206. Accordingly, the Class Period stock sales by Defendant Minogue, COO David Weber, and Director Martin Sutter raise a strong inference of suspicious and unusual trading activity and their trading plans do not provide these insiders with a safe harbor.

**C. The Impella Devices Comprised All of Abiomed’s Revenues; Thus Defendants Knew or Should Have Known of the Slowdown in Growth and Market Saturation.**

207. Abiomed is a medical device company that sells Impella heart pumps. According to both of the Company’s Form 10-Ks filed during the Class Period (for FY18 and FY19) and each signed by Defendants Minogue and Trapp, Abiomed “derive[d], and expect[ed] to continue to derive in the near future, all of our revenues from the sales of our Impella devices.” In FY18, the first year in which the Impella Platform were Abiomed’s only products, Impella product sales alone accounted for 96.1% of the Company’s total annual revenue, and in FY19 it was 96.4%. In 1Q20, the last quarter of the Class Period, Impella product sales accounted for 96.2% of the Company’s revenue for the quarter.

208. Additionally, both prior to and during the Class Period, the Individual Defendants repeatedly made statements emphasizing the importance of the Impella Platform to Abiomed’s growth, as well as touting the expanding adoption of the Impella Platform.

209. For example, on the 4Q18 earnings call held on May 3, 2018, Defendant Trapp stated: “We saw broad-based growth in both the U.S. and outside the U.S. due to continued adoption of the entire Impella platform.” Similarly, on the Company’s 1Q19 earnings call held on July 26, 2018, Defendant Trapp stated the Impella platform gave Abiomed “the ability to make efficient investments in technology, which will lay the groundwork for improving clinical outcomes and sustaining long-term growth.” Additionally, Defendant Minogue, on Abiomed’s 2Q19 earnings call, stated: “We are confident in our future with Impella growth opportunities of several hundred thousand patients, with new and existing indications, new products and new geographies.” In a press release issued on January 31, 2019, Defendant Minogue touted the Company’s “disciplined execution and sustainable growth” stemming from the Impella Platform.

210. Additionally, both the Company’s 2018 and 2019 Form 10-Ks stated: “Our strategic focus and the driver of our revenue growth is the market penetration of our family of Impella heart pumps.”

211. Given that each of the Individual Defendants routinely made statements related to sales of the Impella Platform driving the Company’s revenue growth, as well as the fact that sales of Impella products consisted of more than 96% of the Company’s revenue for each quarter in the Class Period, and the Defendants said that “all” of the Company’s revenue in FY18 and FY19 would be derived from sales of Impella devices, it is unreasonable to think that the Individual Defendants would not be aware that the market for the Impella Platform had been saturated, and revenue growth peaked in 4Q18. Further strengthening that conclusion is that, in addition to participating in the Company’s quarterly earnings calls, each of the Individual Defendants signed Abiomed’s Form 10-Ks.

212. Given the statements made by the Individual Defendants, their positions with the Company, and the fact that the Impella Platform accounted for “all” of the Company’s revenue during the relevant period, the slowdown in Abiomed’s revenue could not have occurred without the Individual Defendants’ knowledge.

## **VII. LOSS CAUSATION/ECONOMIC LOSS**

213. During the Class Period, as detailed herein, Abiomed and the Individual Defendants engaged in a course of conduct that artificially inflated or artificially maintained the price of Abiomed’s securities and operated as a fraud or deceit on all persons and entities who purchased or otherwise acquired Abiomed’s securities during the Class Period.

214. The misstatements and omissions regarding Abiomed’s business concealed risks related to the Company’s inability to sustain its revenue growth and achieve widespread adoption

of the Impella Platform, and it was foreseeable that the value of Abiomed's securities would be adversely affected when the concealed risks materialized.

215. When the hidden risks materialized and became known to the market, the price of Abiomed's securities declined precipitously as the prior artificial inflation was removed from the price of the stock. As a result of their purchases and acquisitions of Abiomed's securities at artificially inflated prices during the Class Period, Plaintiffs and other members of the Class suffered a substantial economic loss (*i.e.*, damages under the federal securities laws). The price decline in Abiomed's securities was a foreseeable and direct result of the nature and extent of the materially false and misleading statements and omissions. Thus, the Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Plaintiffs and the Class.

216. The concealed risks materialized through a series of disclosures beginning on May 2, 2019, before the market opened, with the release of the Company's financial results for the fourth quarter and full year 2019 and concluding on August 1, 2019 with the announcement of the Company's financial results for the first quarter of fiscal year 2020 in which Defendants announced Abiomed's third consecutive quarter of slowing revenue growth and slashed its previously issued full-year 2020 guidance from total revenues in the range of \$900-945 million to total revenues in the range of \$885-925 million, which fell roughly \$22 million short of market expectations.

**A. May 2, 2019 – First Partial Disclosure**

217. The release of the Company's financial results for Q4 2019 and FY 2019 on May 2, 2019, *before the market opened*, was a partial disclosure in which the Company reported revenues of only \$207.7 million, more than \$10 million short of analysts' expectations, and up only 19% as compared to Q3 2019 revenue, and less than half of Q4 2018 growth of 40%.

Impella-related revenues and U.S.-only Impella revenues both fell short of estimates as a result of slower growth in patient utilization.

218. This news—which was at least in part a materialization of the risk concealed by the Class Period misrepresentations and omissions alleged herein—caused Abiomed’s stock price to fall from \$12.30 per share, or approximately 5% from a closing price of \$277.07 per share on May 1, 2019 to a closing price of \$264.77 per share on May 2, 2019. However, the Company’s stock price remained artificially inflated after this announcement as Defendants failed to disclose the full extent of the internal issues frustrating the Company’s revenue growth and ability to expand the adoption of the Impella Platform and falsely assured the market that Abiomed “*already initiated a plan of action to correct the course*” and were “*confident in our innovation and business today as well as long-term outlook for Abiomed.*”

**B. August 1, 2019 – Final Disclosure**

219. The release of the Company’s financial results for the Q1 2020 on August 1, 2019, *before the market opened*, was a materialization of the risk in which the Company announced Abiomed’s third consecutive quarter of slowing revenue growth, reporting Q1 2020 revenue of \$207.7 million, an increase of only 15.4% compared to revenue growth of 36% for Q1 2019. The Company also slashed its previously issued full-year 2020 guidance from total revenues in the range of \$900-945 million to total revenues in the range of \$885-925 million, which fell roughly \$22 million short of market expectations.

220. In reaction to these shocking disclosures—which were a materialization of the risks concealed by the Class Period misrepresentations and omissions alleged herein—Abiomed’s stock price plummeted \$73.69 per share, or 26.45%, to close at \$204.87 per share on August 1, 2019, on usually high trading volume of 4.25 million shares.

### VIII. CLASS ACTION ALLEGATIONS

221. Plaintiff brings this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons and entities who purchased or otherwise acquired the publicly traded securities of Abiomed during the period from May 3, 2018 to July 31, 2019, inclusive, and were damaged thereby (the “Class”). Excluded from the Class are: (i) Defendants; (ii) members of the immediate family of any Defendant who is an individual; (iii) any person who was an officer or director of Abiomed during the Class Period; (iv) any firm, trust, corporation, or other entity in which any Defendant has or had a controlling interest; (v) Abiomed’s employee retirement and benefit plan(s) and their participants or beneficiaries, to the extent they made purchases through such plan(s); and (vi) the legal representatives, affiliates, heirs, successors-in-interest, or assigns of any such excluded person.

222. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, Abiomed’s securities were actively traded on the NASDAQ. While the exact number of Class members is unknown to Plaintiff at this time and can only be ascertained through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by Abiomed or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

223. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class which predominate over questions which may affect individual Class members include:

- (a) whether the Exchange Act was violated by Defendants;

- (b) whether Defendants' statements omitted material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;
- (c) whether Defendants knew or recklessly disregarded that their statements were false and misleading;
- (d) whether the price of the Company's securities was artificially inflated; and
- (e) the extent of damage sustained by Class members and the appropriate measure of damages.

224. Plaintiff's claims are typical of those of the Class because Plaintiff and the Class sustained damages from Defendants' wrongful conduct alleged herein

225. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests that conflict with those of the Class.

226. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

## **IX. APPLICABILITY OF PRESUMPTION OF RELIANCE: FRAUD ON THE MARKET DOCTRINE**

227. Plaintiff alleges that throughout the Class Period, Defendants omitted to disclose material information of which Defendants were aware or were reckless in not knowing. Such statements artificially inflated or artificially maintained the price of Abiomed publicly traded securities and operated as a fraud or deceit on all persons and entities who purchased or

otherwise acquired those securities during the Class Period. Because Defendants chose to speak on the issues described herein, it was important that Defendants not mislead investors or withhold material information. To the extent that the Defendants concealed or improperly failed to disclose material facts with respect to Abiomed's business, Plaintiff is entitled to a presumption of reliance in accordance with *Affiliated Ute Citizens of Utah v. United States*, 406 U.S. 128, 153 (1972).

228. Plaintiff will rely upon the presumption of reliance established by the fraud-on-the-market doctrine in that, among other things:

- (a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- (b) the omissions and misrepresentations were material;
- (c) the Company's securities traded in an efficient market;
- (d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities; and
- (e) Plaintiff and other members of the Class purchased Abiomed's securities between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

229. At all relevant times, the market for Abiomed securities was an efficient market for the following reasons:

- (a) Abiomed securities met the requirements for listing and were listed and actively traded on the NASDAQ, a highly efficient and automated market;
- (b) As a regulated issuer, Abiomed filed periodic public reports with the SEC and the NASDAQ;

(c) Abiomed regularly communicated with public investors via established market communication mechanisms, including regular dissemination of press releases on the national circuits of major newswire services and other wide-ranging public disclosures, such as communications with the financial press and other similar reporting services; and

(d) Abiomed was followed by several securities analysts employed by major brokerage firm(s) including *Morgan Stanley, William Blair, Stephens, Raymond James, Jefferies, and Guggenheim Securities*, which wrote reports that were distributed to the sales force and certain customers of their respective brokerage firm(s) and that were publicly available and entered the public marketplace;

(e) As a result of the foregoing, the market for Abiomed's securities promptly digested current information regarding Abiomed from publicly available sources and reflected such information in Abiomed's securities price(s). Under these circumstances, all persons and entities who purchased or otherwise acquired Abiomed's securities during the Class Period suffered similar injury through their purchase of Abiomed at artificially inflated prices and the presumption of reliance applies.

## X. NO SAFE HARBOR

230. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. The statements alleged to be false and misleading herein all relate to then-existing facts and conditions. To the extent certain statements alleged to be false or misleading are determined to be mixed statements of historical or present information and future information, such statements are not entitled to the safe harbor with respect to the part of the statement that refers to historical or present conditions.

231. To the extent certain of the statements alleged to be false or misleading may be characterized as forward looking, they were not identified as “forward-looking statements” when made and there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements.

232. In the alternative, to the extent that the statutory safe harbor is determined to apply to any forward-looking statements pleaded herein, Defendants are liable for those false forward-looking statements because at the time each of those forward-looking statements were made, the speaker had actual knowledge that the forward-looking statement was materially false or misleading, or the forward-looking statement was authorized or approved by an executive officer of Abiomed who knew that the statement was false when made.

## **XI. CONTROL PERSON ALLEGATIONS**

233. The Individual Defendants, by virtue of their high-level positions with the Company, directly participated in the management of the Company, and were directly involved in the day-to-day operations of the Company at the highest levels. The Individual Defendants participated in drafting, preparing, and/or approving the public statements and communications complained of herein and were aware of, or recklessly disregarded, the material misstatements contained therein and omissions therefrom, and were aware of their materially false and misleading nature.

234. During the Class Period, Defendants’ statements were materially false and misleading when made in that Defendants failed to disclose that:

- (a) The Company’s growth rate was stalling because Impella had reached market penetration – *i.e.*, most hospitals and facilities already stocked Impella products which were used infrequently and rarely required reorder;

(b) The Company could not convince doctors to regularly use the Impella pumps over the IABP, or beyond its narrow indications; thus Abiomed could not achieve significantly greater market penetration or sustain the growth rates the market had become accustomed to from the Company;

(c) Abiomed's revenue growth began to stall as early as May 2018, or Q1 2019, a trend which worsened during the Class Period;

(d) The growth expectations that Abiomed communicated internally to its sales employees and to the market were unattainable, in part, because hospitals were reluctant to stock extra Impella devices in their inventory and doctors remained reluctant to use Impella;

(e) The Company did not have a sufficient plan in place to stem its declining revenue growth; and

(f) Because the Company carefully tracked patient outcomes and sales (including sales results by territory and through Re-Order Reports) and the Individual Defendants participated in meetings and calls, and had access to such sales reports, they knew or recklessly disregarded the deceleration in revenue growth.

(g) Consequently, Defendants' statements during the Class Period regarding the sustainability of the Company's growth and expanded adoption and use of the Impella Platform were materially false and misleading at all relevant times.

235. The Individual Defendants, as senior executive officers of the Company, were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents and statements alleged herein to be materially false and misleading prior to or shortly after their issuance and/or had the ability and opportunity to

prevent their issuance or cause them to be corrected. Accordingly, the Individual Defendants are responsible for the accuracy of the public reports, releases, and other statements detailed herein and are primarily liable for the misrepresentations and omissions contained therein.

236. The Individual Defendants, because of their positions of control and authority as senior executive officers and directors, had access to the adverse undisclosed information about Abiomed's business through their access to internal corporate documents and information, conversations and associations with other corporate officers and employees, attendance at regularly-held meetings, as well as other management and Board of Directors meetings and committees thereof, and reports and other information provided to them in connection therewith.

237. As senior officers and controlling persons of a publicly-held company whose common stock was, during the relevant time, registered with the SEC pursuant to the Exchange Act and traded on the NASDAQ, the Individual Defendants each had a duty to promptly disseminate accurate and truthful information with respect to the Company's operations and business, and to correct any previously issued statements that were or had become materially misleading or untrue, so that the market price of the Company's securities would be based upon truthful and accurate information. The Individual Defendants' wrongdoing during the Class Period violated these specific requirements and obligations.

238. Both of the Individual Defendants are liable as primary participants in a wrongful scheme and course of business that operated as a fraud and deceit on all persons and entities who purchased or otherwise acquired Abiomed's securities during the Class Period, which included the dissemination of materially false and misleading statements (both affirmative statements and statements rendered misleading because of material omission) regarding the Company's deceleration in revenue growth. The scheme: (i) deceived the investing public regarding

Abiomed's operations and the true value of Abiomed's securities; and (ii) caused Plaintiff and other members of the Class to purchase or otherwise acquire Abiomed's securities at artificially inflated prices, which fell as the concealed risks concerning Abiomed's business ultimately became known to the market.

239. In making the statements complained of herein, the Individual Defendants, who were senior officers and controlling persons of Abiomed, were acting on behalf of the Company in the regular course of business. Therefore, each of the statements made by the Individual Defendants is attributable to the Company.

## **XII. CAUSES OF ACTION**

### **COUNT I**

#### **Violation of § 10(b) of the Exchange Act and Rule 10b-5 Promulgated Thereunder (Against All Defendants)**

240. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

241. This Count is asserted against Abiomed and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

242. During the Class Period, Abiomed and the Individual Defendants engaged in a plan, scheme, conspiracy and course of conduct, pursuant to which they knowingly or recklessly engaged in acts, transactions, practices and courses of business which operated as a fraud and deceit upon Plaintiff and the other members of the Class; made various untrue statements of material facts and omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and employed devices, schemes and artifices to defraud in connection with the purchase and sale of securities.

243. Such scheme was intended to, and, throughout the Class Period, did: (i) deceive the investing public, including Plaintiff and other Class members, as alleged herein; (ii) artificially inflate and artificially maintain the market price of Abiomed's securities; and (iii) cause Plaintiff and other members of the Class to purchase or otherwise acquire Abiomed's securities at artificially inflated prices. In furtherance of this unlawful scheme, plan, and course of conduct, Defendants, and each of them, took the actions set forth herein.

244. Pursuant to the above plan, scheme, conspiracy and course of conduct, and by the use of means or instrumentalities of interstate commerce and/or of the mails, each of the Defendants made statements in quarterly and annual reports, SEC filings, press releases and other statements and documents described above, including statements made to securities analysts and the media that were designed to influence the market for Abiomed's securities. Such reports, filings, releases, and statements were materially false and misleading in that they failed to disclose material adverse information and misrepresented risks at Abiomed's business, including its stalled growth.

245. As described above, Abiomed and the Individual Defendants acted with scienter throughout the Class Period, in that they either had actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth in that they failed to ascertain and to disclose the true facts, even though such facts were available to them.

246. The Individual Defendants are liable both directly and indirectly for the wrongs complained of herein. Because of their positions of control and authority, the Individual Defendants were able to and did, directly or indirectly, control the content of the statements of Abiomed. As officers and/or directors of a publicly held company, the Individual Defendants

had a duty to disseminate timely, accurate, and truthful information with respect to Abiomed's businesses, operations, financial condition and prospects.

247. As a result of the dissemination of the aforementioned false and misleading reports, releases and public statements, the market price of Abiomed's securities was artificially inflated throughout the Class Period. In ignorance of the adverse facts concerning Abiomed's business and financial condition that were concealed by Defendants, Plaintiff and the other members of the Class purchased or otherwise acquired Abiomed's securities at artificially inflated prices and relied upon the price of the securities, the integrity of the market for the securities and/or upon statements disseminated by Abiomed and the Individual Defendants, and were damaged thereby.

248. During the Class Period, Abiomed's securities were traded on an active and efficient market. Plaintiff and the other members of the Class, relying on the materially false and misleading statements described herein, which Abiomed and the Individual Defendants made, issued or caused to be disseminated, or relying upon the integrity of the market, purchased or otherwise acquired shares of Abiomed's securities at prices artificially inflated or artificially maintained by Defendants' wrongful conduct.

249. Had Plaintiff and the other members of the Class known the concealed risks, they would not have purchased or otherwise acquired said securities, or would not have purchased or otherwise acquired them at the inflated prices that were paid. At the time of the purchases or acquisitions by Plaintiff and the Class, the true value of Abiomed's securities was substantially lower than the prices paid by Plaintiff and the other members of the Class. The market price of Abiomed's securities declined sharply upon public disclosure of the facts alleged herein, to the injury of Plaintiff and Class members.

250. By reason of the conduct alleged herein, Abiomed and the Individual Defendants knowingly or recklessly, directly or indirectly, have violated Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

251. As a direct and proximate result of the wrongful conduct of Abiomed and the Individual Defendants, Plaintiff and the other members of the Class suffered damages in connection with their purchases and sales of the Company's securities during the Class Period.

## COUNT II

### **Violation of § 20(a) of the Exchange Act (Against Defendants Minogue and Trapp)**

252. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

253. During the Class Period, the Individual Defendants participated in the operation and management of Abiomed, and conducted and participated, directly and indirectly, in the conduct of Abiomed's business affairs. Because of their senior positions, they knew the adverse non-public information about Abiomed's business, including that its market was saturated and its growth rate decelerating.

254. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to Abiomed's financial condition and results of operations, and to promptly correct any public statements issued by Abiomed which had become materially false or misleading.

255. Because of their positions of control and authority as senior officers of Abiomed, the Individual Defendants were able to, and did, control the contents of the various reports, press releases, public filings, and other statements that Abiomed made and disseminated in the marketplace during the Class Period concerning the Company's results of operations. In their

capacities as senior officers of Abiomed, the Individual Defendants had direct involvement in the day-to-day operations of the Company and reviewing and approving the Company's public statements. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause Abiomed to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of Abiomed within the meaning of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged that artificially inflated or artificially maintained the market price of Abiomed's securities.

256. Each of the Individual Defendants, therefore, acted as a controlling person of Abiomed. By reason of their senior management positions and/or being directors of Abiomed, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, Abiomed to engage in the unlawful acts and conduct complained of herein. Both of the Individual Defendants exercised control over the general operations of Abiomed and possessed the power to control the specific activities that comprise the primary violations about which Lead Plaintiff and the other members of the Class complain.

257. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by Abiomed.

### **XIII. PRAYER FOR RELIEF**

WHEREFORE, Plaintiff prays for relief and judgment, as follows:

A. Declaring this action to be a proper class action pursuant to Federal Rule of Civil Procedure 23, certifying Lead Plaintiff as a Class Representative pursuant to Federal Rule of Civil Procedure 23(c), and appointing Labaton Sucharow LLP as Class Counsel pursuant to Rule 23(g);

B. Awarding compensatory damages in favor of Plaintiff and the other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

C. Awarding Plaintiff's reasonable costs and expenses, including attorneys' fees, expert fees, and its other costs and expenses; and

D. Awarding such equitable, injunctive or other relief as the Court may deem just and proper.

**XIV. JURY TRIAL DEMANDED**

Plaintiff hereby demands a trial by jury.

Dated: September 17, 2020

/s/ Christine M. Fox  
Carol C. Villegas  
Christine M. Fox  
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*Attorneys for Lead Plaintiff Local 705  
International Brotherhood of Teamsters  
Pension Fund and Lead Counsel for the Class*

**Appendix A****CLASS PERIOD TRADING OF ABIOMED INSIDERS**

5/3/18 – 7/31/19

Name	Number of Shares	Price	Transaction Value	Transaction Date
Minogue (Michael R)	2,400	\$434.47	\$1,042,728.00	21-Jun-18
Minogue (Michael R)	1,605	\$445.92	\$715,701.60	21-Jun-18
Minogue (Michael R)	3,300	\$443.77	\$1,464,441.00	21-Jun-18
Minogue (Michael R)	3,634	\$441.75	\$1,605,319.50	21-Jun-18
Minogue (Michael R)	5,481	\$436.76	\$2,393,881.56	21-Jun-18
Minogue (Michael R)	6,696	\$440.60	\$2,950,257.60	21-Jun-18
Minogue (Michael R)	1,293	\$442.75	\$572,475.75	21-Jun-18
Minogue (Michael R)	4,325	\$445.17	\$1,925,360.25	21-Jun-18
Minogue (Michael R)	4,165	\$447.01	\$1,861,796.65	21-Jun-18
Minogue (Michael R)	7,984	\$435.63	\$3,478,069.92	21-Jun-18
Minogue (Michael R)	8,009	\$437.88	\$3,506,980.92	21-Jun-18
Minogue (Michael R)	1,000	\$450.06	\$450,060.00	21-Jun-18
Minogue (Michael R)	24,497	\$439.74	\$10,772,310.78	21-Jun-18
Minogue (Michael R)	30,611	\$438.65	\$13,427,515.15	21-Jun-18
<b>Total</b>	105,000		<b>\$46,166,898.68</b>	

Name	Number of Shares	Price	Transaction Value	Transaction Date
Weber (David M)	3,519	\$439.93	\$1,548,113.67	18-Jun-18
Weber (David M)	4,720	\$441.83	\$2,085,437.60	18-Jun-18
Weber (David M)	1,500	\$438.93	\$658,395.00	18-Jun-18
Weber (David M)	500	\$437.07	\$218,535.00	18-Jun-18
Weber (David M)	13,391	\$443.06	\$5,933,016.46	18-Jun-18
Weber (David M)	302	\$446.59	\$134,870.18	18-Jun-18
Weber (David M)	2,684	\$440.81	\$1,183,134.04	18-Jun-18
Weber (David M)	12,410	\$443.87	\$5,508,426.70	18-Jun-18
Weber (David M)	1,000	\$445.77	\$445,770.00	18-Jun-18
Weber (David M)	1,900	\$437.86	\$831,934.00	18-Jun-18
Weber (David M)	4,574	\$444.81	\$2,034,560.94	18-Jun-18
Weber (David M)	100	\$362.64	\$36,264.00	30-Jul-18
Weber (David M)	4,794	\$356.23	\$1,707,766.62	30-Jul-18
Weber (David M)	2,400	\$355.13	\$852,312.00	30-Jul-18
Weber (David M)	400	\$360.85	\$144,340.00	30-Jul-18
Weber (David M)	1,200	\$358.15	\$429,780.00	30-Jul-18
Weber (David M)	1,500	\$359.06	\$538,590.00	30-Jul-18
Weber (David M)	400	\$363.05	\$145,220.00	30-Jul-18
Weber (David M)	2,087	\$354.18	\$739,173.66	30-Jul-18
Weber (David M)	400	\$360.38	\$144,152.00	30-Jul-18
Weber (David M)	1,000	\$353.26	\$353,260.00	30-Jul-18
Weber (David M)	4,001	\$357.09	\$1,428,717.09	30-Jul-18
Weber (David M)	300	\$363.96	\$109,188.00	30-Jul-18
Weber (David M)	100	\$365.00	\$36,500.00	30-Jul-18
Weber (David M)	400	\$352.15	\$140,860.00	30-Jul-18
Weber (David M)	200	\$365.91	\$73,182.00	30-Jul-18
Weber (David M)	5,965	\$351.46	\$2,096,458.90	25-Jan-19
Weber (David M)	10,195	\$350.37	\$3,572,022.15	25-Jan-19
Weber (David M)	4,850	\$352.63	\$1,710,255.50	25-Jan-19
Weber (David M)	2,990	\$353.32	\$1,056,426.80	25-Jan-19
<b>Total</b>	89,782		<b>\$35,896,662.31</b>	

Name	Number of Shares	Price	Transaction Value	Transaction Date
Sutter (Martin P)	400	\$345.64	\$138,256.00	8-May-18
Sutter (Martin P)	800	\$340.42	\$272,336.00	8-May-18
Sutter (Martin P)	400	\$346.26	\$138,504.00	8-May-18
Sutter (Martin P)	700	\$345.38	\$241,766.00	8-May-18
Sutter (Martin P)	3,950	\$343.77	\$1,357,891.50	8-May-18
Sutter (Martin P)	200	\$341.84	\$68,368.00	8-May-18
Sutter (Martin P)	1,400	\$344.69	\$482,566.00	8-May-18
Sutter (Martin P)	5,300	\$343.66	\$1,821,398.00	8-May-18
Sutter (Martin P)	400	\$342.00	\$136,800.00	8-May-18
Sutter (Martin P)	2,700	\$342.67	\$925,209.00	8-May-18
Sutter (Martin P)	2,757	\$342.79	\$945,072.03	8-May-18
Sutter (Martin P)	283	\$346.54	\$98,070.82	8-May-18
Sutter (Martin P)	1,900	\$344.55	\$654,645.00	8-May-18
Sutter (Martin P)	700	\$340.47	\$238,329.00	8-May-18
Sutter (Martin P)	2,395	\$351.46	\$841,746.70	4-Feb-19
Sutter (Martin P)	17,548	\$350.12	\$6,143,905.76	4-Feb-19
Sutter (Martin P)	4,072	\$350.05	\$1,425,403.60	5-Feb-19
Sutter (Martin P)	5,369	\$350.00	\$1,879,150.00	6-Feb-19
Sutter (Martin P)	616	\$345.00	\$212,520.00	6-Feb-19
Sutter (Martin P)	5,000	\$360.00	\$1,800,000.00	13-Feb-19
Sutter (Martin P)	5,000	\$360.00	\$1,800,000.00	14-Feb-19
Sutter (Martin P)	8,919	\$360.23	\$3,212,891.37	15-Feb-19
Sutter (Martin P)	1,081	\$361.00	\$390,241.00	15-Feb-19
Sutter (Martin P)	801	\$257.88	\$206,561.88	8-May-19
Sutter (Martin P)	566	\$261.04	\$147,748.64	8-May-19
Sutter (Martin P)	1,100	\$259.06	\$284,966.00	8-May-19
Sutter (Martin P)	1,297	\$260.10	\$337,349.70	8-May-19
Sutter (Martin P)	900	\$262.08	\$235,872.00	8-May-19
<b>Total</b>	76,554		<b>\$26,437,568.00</b>	
<b>Total Shares Sold During Class Period and Proceeds</b>	271,336		<b>\$ 108,501,128.99</b>	

**CONTROL PERIOD TRADING**  
2/2/17 – 5/2/18

Name	Number of Shares	Price	Proceeds	Transaction Date
Weber (David M)	6,361	\$108.66	\$691,186.26	6-Feb-17
Weber (David M)	6,130	\$107.72	\$660,323.60	6-Feb-17
Weber (David M)	5,059	\$109.78	\$555,377.02	6-Feb-17
Weber (David M)	3,200	\$106.89	\$342,048.00	6-Feb-17
Weber (David M)	500	\$105.37	\$52,685.00	6-Feb-17
Weber (David M)	900	\$132.57	\$119,313.00	8-May-17
Weber (David M)	14,350	\$130.55	\$1,873,392.50	8-May-17
Weber (David M)	6,000	\$131.45	\$788,700.00	8-May-17
Weber (David M)	8,300	\$147.28	\$1,222,424.00	31-Jul-17
Weber (David M)	8,200	\$147.98	\$1,213,436.00	31-Jul-17
<b>Total</b>	<b>59,000</b>		<b>\$7,518,885.38</b>	
<i><b>Total Shares Sold During Class Period and Proceeds</b></i>	<b>59,000</b>		<b>\$7,518,885.38</b>	

**CERTIFICATION**

I, Jack Witt, as Fund Administrator of Local 705 International Brotherhood of Teamsters Pension Fund (“Local 705”), hereby certify as follows:

1. I am fully authorized to enter into and execute this Certification on behalf of Local 705. I have reviewed a Complaint prepared against ABIOMED, Inc. (“ABIOMED”) alleging violations of the federal securities laws and authorize the filing of this pleading;
2. Local 705 did not purchase securities of ABIOMED at the direction of counsel or in order to participate in any private action under the federal securities laws;
3. Local 705 is willing to serve as a lead plaintiff and representative party in this matter, including providing testimony at deposition and trial, if necessary. Local 705 fully understands the duties and responsibilities of the lead plaintiff under the Private Securities Litigation Reform Act, including the selection and retention of counsel and overseeing the prosecution of the action for the Class;
4. Local 705’s transactions in ABIOMED securities during the Class Period are reflected in Exhibit A, attached hereto;
5. Local 705 sought to serve as a lead plaintiff in the following class action filed under the federal securities laws during the last three years:

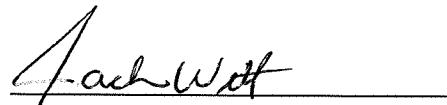
*Villare v. ABIOMED, Inc.*, No. 1:19-cv-7319 (S.D.N.Y.)  
*Klein v. Altria Group, Inc.*, No. 2:19-cv-5579-FB-AKT (E.D.N.Y.)

6. Local 705 sought to serve as a representative party but not as a lead plaintiff in the following class action filed under the federal securities laws during the last three years:

*Local 705 International Brotherhood of Teamstrs Pension Fund v. Diamond Resorts International, Inc.*,  
No. 2:18-cv-1355 (D. Nev.)

7. Beyond its pro rata share of any recovery, Local 705 will not accept payment for serving as a lead plaintiff and representative party on behalf of the Class, except the reimbursement of such reasonable costs and expenses (including lost wages) as ordered or approved by the Court.

I declare under penalty of perjury, under the laws of the United States, that the foregoing is true and correct this 16<sup>th</sup> day of September, 2020.



Jack Will  
Fund Administrator  
*Local 705 International Brotherhood of Teamsters  
Pension Fund*

**EXHIBIT A****TRANSACTIONS IN ABIOMED, INC.**

<b>Transaction Type</b>	<b>Trade Date</b>	<b>Shares</b>	<b>Price Per Share</b>	<b>Cost / Proceeds</b>
Sale	06/20/18	-480.00	\$444.48	\$213,349.30
Purchase	01/24/19	1,579.00	\$347.30	(\$548,384.49)
Purchase	01/24/19	20.00	\$342.50	(\$6,850.08)
Purchase	01/24/19	57.00	\$342.03	(\$19,495.92)
Purchase	02/11/19	172.00	\$354.05	(\$60,895.74)
Purchase	02/11/19	278.00	\$353.52	(\$98,279.89)
Purchase	02/12/19	398.00	\$357.50	(\$142,285.80)
Purchase	02/20/19	551.00	\$359.45	(\$198,054.91)
Purchase	02/21/19	276.00	\$359.12	(\$99,116.98)
Purchase	03/18/19	439.00	\$331.58	(\$145,563.05)
Purchase	03/19/19	248.00	\$338.79	(\$84,019.23)
Purchase	03/19/19	22.00	\$334.23	(\$7,353.02)
Purchase	03/19/19	15.00	\$332.96	(\$4,994.39)
Purchase	03/20/19	24.00	\$341.91	(\$8,205.91)
Purchase	03/26/19	194.00	\$286.58	(\$55,596.77)
Sale	05/16/19	-167.00	\$263.56	\$44,014.84
Purchase	05/24/19	451.00	\$271.47	(\$122,434.46)
Purchase	06/26/19	75.00	\$251.60	(\$18,869.73)